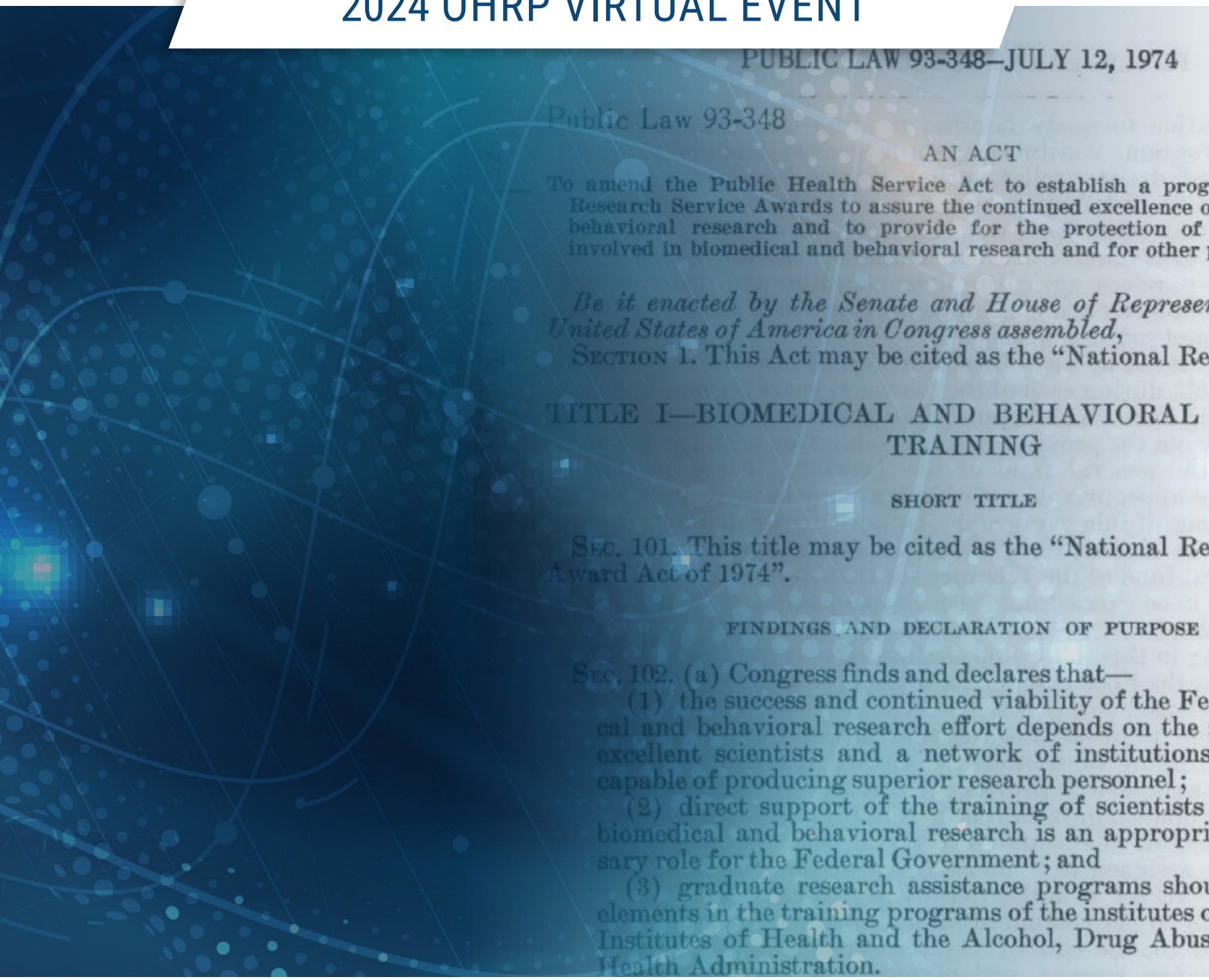
COMMEMORATING THE 50TH ANNIVERSARY OF THE NATIONAL RESEARCH ACT

https://www.hhs.gov/ohrp/education-and-outreach/national-research-act-50th-anniversary/index.html

2024 OHRP VIRTUAL EVENT


PUBLIC LAW 93-348—JULY 12, 1974

Public Law 93-348

AN ACT

To amend the Public Health Service Act to establish a prog
Research Service Awards to assure the continued excellence o
behavioral research and to provide for the protection of
involved in biomedical and behavioral research and for other

Be it enacted by the Senate and House of Represe
United States of America in Congress assembled,
SECTION 1. This Act may be cited as the "National Re

TITLE I—BIOMEDICAL AND BEHAVIORAL
TRAINING

SHORT TITLE

SEC. 101. This title may be cited as the "National Re
Award Act of 1974".

FINDINGS AND DECLARATION OF PURPOSE

SEC. 102. (a) Congress finds and declares that—
(1) the success and continued viability of the Fe
cal and behavioral research effort depends on the
excellent scientists and a network of institutions
capable of producing superior research personnel;
(2) direct support of the training of scientists
biomedical and behavioral research is an appropri
sary role for the Federal Government; and
(3) graduate research assistance programs shou
elements in the training programs of the institutes o
Institutes of Health and the Alcohol, Drug Abus
Health Administration.

OASH | Office for Human Research Protections

Program Book

INTRODUCTION

July 12, 2024, marked the 50th anniversary of the enactment of the National Research Act. The National Research Act was a response to public outcry that the federal government let hundreds of Black men in rural Alabama go untreated for syphilis for 40 years to study the impact of the disease on the human body. The Act included creation of federal rules to protect human participants in research. It also led to the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to identify ethical standards to guide human research. This OHRP commemorative event reflected on what happened following the passage of the National Research Act, showcased the diverse role research participants play in contemporary research, and considered what future scientific advances may mean for research participants and public trust in research.

AGENDA

Time	Sessions
Session Title	**Opening**
12:00 p.m.– 12:15 p.m.	• **OHRP's Welcome** • **ASH's Address**
Session Title	**What Followed the National Research Act**
12:15 p.m.– 12:50 p.m.	**1. Reflections on the Work of the National Commission** The former Commissioner of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research spoke about her experience serving on the Commission, her reflections on the Commission's work, and its impact on research. **Speaker: Patricia A. King, J.D.**; *Professor Emerita, Georgetown Law* **2. The Evolution of the Regulations for Human Research Protections and the Establishment of OHRP** The OHRP speaker provided a brief overview of the National Research Act, described how the initial regulations came about, and how the Office for Human Research Protections was established. **Speaker: Ivor A. Pritchard, Ph.D.**; *Senior Advisor to the Director of the HHS Office for Human Research Protections (ret)* **3. A Brief History of Public Responsibility in Medicine and Research (PRIM&R) – A Response from the Research Community** The Executive Director of PRIM&R provided a historical overview of the nonprofit founded 50 years ago as a response to the new law requiring the development of guidelines and laws to oversee and regulate human research, and offered an account of how the organization came about, what role it hoped to play, and how it would achieve its objective. **Speaker: Ivy Tillman, Ed.D.**; *Executive Director of PRIM&R*
Session Title	**From Research Subject to Research Partner**
12:50 p.m.– 1:45 p.m.	*Fifty years after the passage of the National Research Act, people are no longer seen as merely "subjects" in research but are now regarded as integral partners. This session showcased the different ways the public may be engaged in the research process to advance science and further their interests as individuals and members of a community.* **1. Why I Participated in Research - A Participant's Voice** A former participant reflected on their experience in research and addressed how participating led them to a career in research recruitment and coordination involving teenagers and young adults. **Speaker: Rey Calabrese**; *Former Research Participant and Current Research and Community Coordinator at Fenway Health* **2. Participants as Investigators: Participatory Action Research and Community-Led Studies** Community research coordinators have an increasing role in research, especially in social, behavioral, and education studies. A community research coordinator discussed how, as a member of the local community, he became involved in community participatory-action research and the role he and participants have played in facilitating meaningful research for their communities. **Speaker: Basaime Spate**; *Community Research Coordinator, Center for Justice Innovation*

AGENDA

Time	Sessions
Session Title	**From Research Subject to Research Partner**
12:50 p.m.– 1:45 p.m.	**3. Respecting Cultural Values: Doing Research with Indigenous Populations** An enrolled member of the Choctaw Nation of Oklahoma with a deep commitment to engaging tribal leadership in community-based participatory health research discussed efforts taken to build research partnerships with tribal nations while ensuring respect for cultural values and interests. **Speaker: Karina L. Walters, Ph.D., M.S.W.**; *Director, NIH's Tribal Health Research Office (THRO)* **4. Listening to the People: Community Ethics Review Boards** Community Ethics Boards are one way in which the community can give feedback and improve research proposals. A member of a Community Ethics Board discussed how they advise researchers on the community's needs, perspectives, and values, and ultimately shape local research. **Speaker: Ella Greene-Moton**; *Member of a Community Ethics Board in Flint, MI, and President of the American Public Health Association* **5. Engaging the Community in Research: The Insight of an Investigator** Community engagement has become an important part of a successful research program. Dr. Aguilar-Gaxiola shared his insights on why this is important, the benefits it brings to research, what he's learned from the communities he's worked with, and how this has enriched him as a researcher. **Speaker: Sergio Aguilar-Gaxiola, M.D., Ph.D.**; *Professor of Clinical Internal Medicine; Director, Center for Reducing Health Disparities (CRHD); Director, Community Engagement Program of the Clinical Translational Science Center (CTSC), University of California, Davis, School of Medicine*
Session Title	**Contemplating the Future**
1:45 p.m. – 2:30 p.m.	*Speakers in this panel discussion explored the potential impact of scientific advances in the coming decades, the challenges they may present to the notion of "human research protection," the stress they may put on public trust, and what the scientific community can do and prepare for it.* **Moderator:** **Laura Ruse Brosch, R.N., Ph.D., COL., AN, USA (ret)**; *Assistant Vice President for Research Initiatives and Compliance, Office of the Vice President for Research, Uniformed Services University of the Health Sciences* **Panelists:** **Jodi Halpern, M.D., Ph.D.**; *Chancellor's Chair and Professor of Bioethics, UC Berkeley* **Misha Angrist, Ph.D., M.F.A.**; *Associate Professor of the Practice, Social Science Research Institute, Senior Fellow Duke Initiative for Science & Society, Visiting Associate Professor of the Practice, Sanford School of Public Policy* **Lee McIntyre, Ph.D.**; *Research Fellow, Center for Philosophy and History of Science, Boston University* **Aaron F. Mertz, Ph.D.**; *Director, Science and Society, Aspen Institute*

SPEAKER BIOGRAPHIES

Session I

Patricia A. King, *J.D.*
Professor Emerita, Georgetown Law

Patricia King is Professor of Law emerita at Georgetown University Law School. Her scholarship focuses on race and genomics, racial disparities in health, and reproductive health. She is a member of the National Academy of Medicine, a Fellow of the Hastings Center and a faculty affiliate of Georgetown's Kennedy Institute of Ethics. She has served on numerous national advisory bodies formed to address the ethical issues generated by developments in science and technology, including the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-78) that produced the seminal "Belmont Report," the President's Advisory Committee on Human Radiation Experiments (1994-95), the National Institutes of Health (NIH) Embryo Research Panel, the Ethics, Legal, and Social Issues Working Group of the NIH Human Genome Project (1989-95), and the NIH Recombinant DNA Advisory Committee (1979-81).

Professor King has served on several corporate and foundation boards. In addition, she is a graduate of Wheaton College (MA) and chaired its board for five years. She is also a graduate of Harvard Law School and served on the Harvard Corporation, the governing body of Harvard University. She has received honorary degrees from Wheaton College, Harvard University, and Old Dominion University.

Ivor A. Pritchard, *Ph.D.*
Senior Advisor to the Director, HHS Office for Human Research Protections (ret)

Ivor Pritchard, Ph.D., is the recently retired Senior Advisor to the Director of OHRP in the Office for Human Research Protections (OHRP) in the Department of Health and Human Services. He came to OHRP in 2004 from the Institute for Education Sciences at the U.S. Department of Education, where he was a Senior Research Analyst. He joined the U.S Department of Education in 1986. He has a Ph.D. in philosophy from Boston University. Dr. Pritchard authored or co-authored many publications including "Students as Research Subjects" (with Koski, *Encyclopedia of Bioethics*, 2014); "How Do IRB Members Make Decisions? A Review and Research Agenda" (*Journal of Empirical Research on Human Research Ethics*, 2011), "Searching for 'Research Involving Human Subjects': What Is Examined? What Is Exempt? What Is Exasperating?" (IRB: *Ethics & Human Research*, 2001); "Travelers and Trolls: Practitioner Research and Institutional Review Boards" (*Educational Researcher*, 2002); *Ethical Standards of the American Educational Research Association: Cases and Commentary* (Strike et al., 2002); and "Power, Truth and Justice in Youth Participatory Action Research: Ethical Questions" *(Practicing Anthropology: A Career-Oriented Publication of the Society for Applied Anthropology*, 2004.) His research interests include research ethics and federal policy, moral and civic education research and practice, and education policy.

Ivy Tillman, *Ed.D.*
Executive Director, PRIM&R

Ivy Tillman, Ed.D., CCRC, CIP, is the Executive Director of PRIM&R, advancing PRIM&R's mission of promoting the highest ethical standards in the conduct of research through critical research policy expertise, professional development, and education to its community of professionals. Dr. Tillman brings over 18 years of leadership in research ethics and oversight, focusing on promoting the trustworthiness of research organizations. As a purposeful leader, Dr. Tillman has developed partnerships with a variety of stakeholders, bringing varied perspectives and voices together to create programs and initiatives that move research ethics conversations forward.

Session II

Rey Calabrese
Former Research Participant; Current Research and Community Coordinator, Fenway Health

Rey Calabrese is a former research participant and is currently the Research and Community Coordinator at Fenway Health.

Basaime Spate
Community Research Coordinator, Center for Justice Innovation

Basaime Spate is a Community Research Coordinator at the Center for Justice Innovation.

Karina L. Walters, *Ph.D., M.S.W.*
Director, NIH Tribal Health Research Office (THRO)

Karina L. Walters, PhD, MSW, an enrolled member of the Choctaw Nation of Oklahoma, is Director of the NIH Tribal Health Research Office (THRO). In this role, she leads the THRO team and works to unify NIH representatives, research, and resources to improve the health of American Indians and Alaska Natives. She is deeply committed to engaging Tribal leadership in health research efforts. A social epidemiology and health prevention scholar, Dr. Walters has more than 28 years of Native health research experience, encompassing foundational science, disease prevention, health promotion, and intervention research. Prior to NIH, she was a tenured full professor and the Katherine Hall Chambers Scholar at the University of Washington (UW) School of Social Work. She is also the founding director of the UW Indigenous Wellness Research Institute and served from 2012-2019 as Associate Dean for Research at the UW School of Social Work. Dr. Walters is the first American Indian fellow inducted into the American Academy of Social Welfare and Social Work. She earned a bachelor's degree in sociology from the University of California, Los Angeles (UCLA) and an M.S.W. and a Ph.D. in social welfare, also from UCLA.

Ella Greene-Moton

Member of a Community Ethics Board in Flint, Michigan; President, American Public Health Association

Ella Greene-Moton has an extensive background in public health advocacy, public health policy, community-based participatory research, and programming spanning the past 40+ years in the City of Flint and surrounding areas. In addition, specific efforts in public health ethics have focused on providing an awareness at the community level, developing and elevating the community voice and advocating for community inclusiveness at the state and national Levels. Her areas of expertise include facilitating community/academic/practice partnership building and sustainability; developing, managing, and evaluating community-based projects; and developing training programs for graduate students and community members, as well as middle and high school students partnering with community-based organizations, schools, and public health agencies. Ms. Greene-Moton joined the Flint Odyssey House, Inc., Health Awareness Center in 1995 and served as its assistant director from 1998-2005. She served from 2006-2019 as a community education coordinator and "Bridge" at the Center for Public Health and Community Genomics at the School of Public Health at the University of Michigan - Ann Arbor. She currently serves as the Community Based Organization Partners Community Ethics Review Board administrator and the executive consultant and co-chair of the Flint/Genesee Partnership, Health in Our Hands project. She also serves as an independent community-academic consultant working with other academic institutions nationally that are engaged in community-based participatory research. On the state, regional, and national levels, Ms. Greene-Moton is a member of the Michigan Public Health Association Board of Directors and serves as the Michigan Affiliate Representative to the Governing Council of the American Public Health Association. She represents Michigan on the Great Lakes Public Health Coalition and serves as the Regional Representative for Region V on the Council on Affiliates. In addition, and along with five of her MIPHA colleagues, Ms. Greene-Moton serves as a Cohort 10 and 11 Fellow of the Leadership Academy for the Public's Health Michigan Health Equity Team.

Sergio Aguilar-Gaxiola, *M.D., Ph.D.*

Founding Director, Center for Reducing Health Disparities at UC Davis Health; Director of the Community Engagement Program, UCD Clinical Translational Science Center (CTSC)

Sergio Aguilar-Gaxiola, M.D., Ph.D. is a Professor of Clinical Internal Medicine at the School of Medicine, University of California, Davis. He is the Founding Director of the Center for Reducing Health Disparities at UC Davis Health and the Director of the Community Engagement Program of the UCD Clinical Translational Science Center (CTSC). Dr. Aguilar-Gaxiola's applied and translational research program has focused on identifying unmet health and mental health needs and associated risk and protective factors to better meet population health and mental health needs and advance equity in health and mental health in underserved populations. He and his team are committed to developing, implementing, evaluating, and disseminating innovative models of health/mental health service delivery where patients are at (where they live, work, congregate). Dr. Aguilar-Gaxiola is the author of over 210 publications. He is the recipient of multiple international, national, state, and local awards.

Session III

Laura Ruse Brosch, *R.N., Ph.D., COL, AN, USA (ret)*
Assistant Vice President for Research Initiatives and Compliance, Office of the Vice President for Research, Uniformed Services University of the Health Sciences

Laura Ruse Brosch serves as the Assistant Vice President for Research Initiatives and Compliance at the Uniformed Services University in Bethesda, Maryland. With 40 years of federal service, including 26 years on active military duty, she brings extensive experience, notably as the past Director of the Office of Research Protections at the US Army Medical Research and Materiel Command. In this role, she spearheaded global human research protection efforts for the military. A retired Colonel in the Army Nurse Corps, Dr. Brosch specializes in research protections across various military interest areas and actively contributes to the ethical evaluation of emerging Department of Defense technologies. Holding a Ph.D. from the University of Maryland, Baltimore, she has received awards such as the Anita Newcomb McGee Award and the Jonathan Letterman Award for her significant contributions to military medicine. Dr. Brosch's commitment to transparent research protections and support for challenging research endeavors define her distinguished career.

Jodi Halpern, *M.D., Ph.D.*
Chancellor's Chair and Professor of Bioethics, UC Berkeley

Jodi Halpern M.D., Ph.D., Chancellor's Chair and Professor of Bioethics at University of California, Berkeley, is an international leader on empathy in healthcare, respect for the rights of patients and human subjects of research, and the ethics of innovative technologies including AI, gene editing, and neurotechnology. Dr. Halpern's book *From Detached Concern to Empathy: Humanizing Medical Practice* catalyzed a wave of change in medicine. Her book *Remaking the Self in the Wake of Illness* (expected 2024) illuminates post-traumatic growth. Her newest project, Engineering Empathy, examines AI and therapeutic relationships. Halpern co-founded the Berkeley Group on Ethics and Regulation of Innovative Technologies and the UC Berkeley Kavli Institute for Ethics, Science, and the Public. Halpern received the Guggenheim 2022 Award in Medicine and Health.

Misha Angrist, *Ph.D., M.F.A.*
Associate Professor of the Practice, Social Science Research Institute; Senior Fellow, Duke Initiative for Science & Society; Visiting Associate Professor of the Practice, Sanford School of Public Policy

Misha Angrist is Associate Professor of the Practice in Duke University's Social Science Research Institute and a Senior Fellow in its initiative for Science & Society. He holds an M.S. in genetic counseling, a Ph.D. in genetics, and an M.F.A. in writing. He is interested in the intersection of biology and society, especially as it relates to the governance of human participation in research and medicine. At Duke, his courses include "Responsible Conduct of Research" and "Law, Research, and Bioethics." As the fourth participant in the Personal Genome Project, he was among the first to have his entire genome sequenced and made public, an experience he chronicled in the book *Here Is a Human Being: At the Dawn of Personal Genomics*. He served on the Duke University Health System IRB for five years and currently serves on the Genetic Alliance IRB.

Lee McIntyre, *Ph.D.*
Research Fellow, Center for Philosophy and History of Science, Boston University; Senior Advisor for Public Trust in Science, Aspen Institute

Lee McIntyre is a Research Fellow at the Center for Philosophy and History of Science at Boston University and Senior Advisor for Public Trust in Science at the Aspen Institute. He previously taught philosophy at Colgate University, Boston University, Simmons University, Tufts Experimental College, and Harvard Extension School. McIntyre is the bestselling author of *Post-Truth* (MIT Press, 2018), which was named a CNN Book-of-the-Week in April 2018 and a Best Book of 2018 by the PBS News Hour, along with numerous other books including *The Scientific Attitude* (2019), *How to Talk to a Science Denier* (2021), and *On Disinformation* (2023), all published with MIT Press. His popular essays have appeared in the *New York Times*, *Washington Post*, *Boston Globe*, *Baltimore Sun*, *Nature*, and *Newsweek*. He has appeared on CNN, PBS, MSNBC, NPR, and the BBC, and has spoken at the United Nations, NASA, and the Vatican.

Aaron F. Mertz, *Ph.D.*
Director, Science and Society, Aspen Institute

Internationally recognized for his laboratory research and science advocacy, Aaron Mertz joined the Aspen Institute in 2019 as the founding Director of the Science & Society Program. He enacts projects and initiatives that test ideas to explain, connect, and maximize the benefits of science for the public good. Notable efforts include a youth initiative connecting science and social justice and a forthcoming feature-length documentary about professional challenges facing scientists. Earlier, he was an NSF Postdoctoral Fellow at Rockefeller University. His publications span biology, physics, engineering, and science policy and have appeared in *Nature*, *Science*, *Cell*, *Proceedings of the National Academy of Sciences*, and *Physical Review Letters*. He earned a bachelor's degree in physics from Washington University in St. Louis as a Goldwater Scholar, a master's degree in the history of science from the University of Oxford as a Rhodes Scholar, and a doctorate in physics from Yale University as an NSF Graduate Research Fellow and Beckman Fellow.

SUMMARY REPORT

CONTENTS

OPENING

OHRP's Welcome

Ms. Julie Kaneshiro, Acting Director of OHRP, stressed that while the past 50 years have brought significant progress in protecting human research subjects, science and technology continually advance. With these changes, the ethical complexity of choices to be made by stakeholders in human subject protection presents new challenges, requiring the research community to be thoughtful about its ethical responsibilities in new situations. OHRP remains committed to its mission. Going forward, Ms. Kaneshiro said, we will build together on the foundation provided by the National Research Act to meet future challenges.

Ms. Kaneshiro expressed her thanks to all the panelists and those in attendance.

Address by the Assistant Secretary of Health

Admiral Rachel Levine, M.D., Assistant Secretary of Health (ASH), reminded attendees that the National Research Act emerged from atrocities committed by the U.S. Public Health Service. Researchers monitored hundreds of African American men with syphilis and opted to withhold treatment. The study caused irreparable harm, mistrust, and suffering. The Act was born from the public outcry that followed an account of the study published by the New York Times.

The Act is far more than a law. It commits the United States to a future in which ethical principles are paramount and the pursuit of knowledge does not come at the cost of dignity and human rights. We have made progress in ensuring that our partners in research are given due respect, Admiral Levine said, but our work is ongoing. Today's commemorative event is a renewed promise to the American people that we will never stop working for safety, inclusion, and justice in human subjects research.

Dr. Yvonne Lau, Director of OHRP's Division of Education and Development, thanked Admiral Levine and expressed appreciation for the enthusiastic support of each of the invited speakers. She looked forward to a meaningful reflection on past, present, and the future.

WHAT FOLLOWED THE NATIONAL RESEARCH ACT

1. Reflections on the Work of the National Commission

Speaker: Patricia A. King, J.D.
Professor Emerita, Georgetown Law

Professor King recalled her experience of being a member of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which was established in 1974 and met for four years. The Commission's impact has been substantial in advancing ethical research involving human subjects. It issued multiple reports on fetuses, children, and the "mentally infirm" in institutions. In the seminal Belmont Report, its best-known product, it articulated ethical principles that should govern research.

After meeting the other members of the Commission, Professor King at first thought herself an unlikely member. She had no connection to medicine or philosophy, but she had served as the Director of the Office of Civil Rights for the then-Department of Health, Education, and Welfare (HEW), later the Department of Health and Human Services (HHS). As a lawyer and a Black woman, she had a working knowledge of the egregious study that had sparked the Commission's mandate.

The Commission spent little time discussing this study, Professor King recalled. Nor did it spend much time revisiting the work of past groups. In retrospect, she felt it was unfortunate that the Commission did not examine the study in more depth, as it might have alerted members to the limitations of the principle of respect for persons and the need for a deeper dive into the principle of justice. She felt the Commission had not understood and expressed everything that it needed to articulate related to justice as an ethical principle.

The Commission's first task was to deliver a report on ethical issues in fetal research within 4 months, which it accomplished. While many members were familiar with these issues, they were less familiar with those that arose in relation to protections for prisoners. Previous deliberations were informative, including the Nuremberg Code of Ethics. However, to understand issues related to informed consent, members needed to visit prisons and meet with prisoners. Professor King recalled the powerful statement of one prisoner at Jackson State prison: "Ladies and gentlemen: You are in a place where death at random is a way of life. We have noticed that the only place in this prison that people don't die is in the research unit. Just what is it that you think you are protecting us from?" In the end, the Commission's recommendations related to prisons were not adopted because it was thought that the concerns expressed were beyond HEW's control and would require an examination of the entire structure of the prison system.

2. The Evolution of the Regulations for Human Research Protections and the Establishment of OHRP

Speaker: Ivor A. Pritchard, Ph.D.
Senior Advisor to the Director of the HHS Office for Human Research Protections (ret)

Dr. Pritchard noted that the U.S. Public Health Service Study of Untreated Syphilis (1932-72) had not been hidden and had generated several reports in the scientific literature. When it was brought to public attention, however, it triggered Congressional hearings spearheaded by Senator Edward Kennedy that contributed to the formation of the National Research Act. The testimony highlighted issues such as these:

- Emerging technology and the ethical issues that arise
- Widespread prescription of FDA-approved drugs for unapproved uses
- Psychosurgical practices and the possibility of control of human behavior
- Ethical issues related to research involving prisoners
- Involuntary sterilization practices taking place in various parts of the country
- Funding for research and research training (the existing budget had substantially reduced funds available)
- The ethical implications of genetic research (for example, cloning and the need for counseling on findings)

The National Research Act of 1974 had two Titles. Title I provided $1.38 billion (in 2024 dollars) for research-related training. Title 2, Protection of Human Subjects of Biomedical and Behavioral Research, called for the following actions:

- Created The National Commission
- Directed that the National Advisory Council for the Protection of Subjects be put in place after the Commission's advice was received (this was never done)
- Directed that there be regulations from HEW for the establishment of Institutional Review Boards (IRBs)
- Called for an HEW Program for clarification and guidance on ethical issues in biomedical and behavioral research
- Proposed increased emphasis on bioethics training in medical schools
- Placed a temporary ban on research involving the fetus until the first report from the Commission, which would address related ethical issues

The charges to the National Commission included:

- Identify the basic ethical principles for the conduct of biomedical and behavioral research involving human subjects, including the boundary between research and the practice of medicine
- Consider ethical issues related to research involving children, prisoners, and persons institutionalized as "mentally infirm"
- Consider how ethical issues in research not subject to the Secretary's regulations should be addressed
- Consider issues related to psychosurgery (not necessarily in the context of research)
- Study the ethical, legal and social implications of advances in research and technology

What actually happened as a result of the National Research Act, including the work of the Commission?
Dr. Pritchard observed:

- Funding for training sponsored by the National Institutes of Health was increased.

- The Office for Protection from Research Risks (OPRR)—now the OHRP—was created.
- A series of reports by the Commission, including the Belmont Report, was issued. However, no action was taken on its recommendations related to research involving the institutionalized "mentally infirm," which were considered too controversial, or as previously noted, its recommendations on prisoners.
- Regulations for the Protection of Human Subjects in Research became effective July 1, 1974.

Dr. Pritchard noted that HEW Regulations were revised based on the Commission's recommendations and became effective July 27,1981. The Common Rule, which became law on August 19, 1991, dramatically expanded the jurisdiction of the regulations to apply to research carried out by multiple federal agencies. The Common Rule was revised and generally became effective January 21, 2019. The current Rule is referred to as "the 2018 requirements."

Originally, OPRR reported to the Director of the National Institutes of Health (NIH). As it became more assertive about taking compliance actions against agencies it considered not to be providing appropriate protections, controversy arose and led to the office being renamed and transferred to the Office of Public Health and Science under the Assistant Secretary of Health (1999). The new office of OHRP was charged with oversight for all research conducted or supported by HHS and with advising the agency on ethical issues related to both biomedical and behavioral research.

3. A Brief History of Public Responsibility in Medicine and Research (PRIM&R)–A Response from the Research Community

Speaker: Ivy Tillman, Ed.D.
Executive Director of PRIM&R

Dr. Tillman, the third Executive Director of Public Responsibility in Medicine and Research (PRIM&R), explained that the organization was founded during the development of the National Research Act, which became the cornerstone of its mission: to support the community of research professionals in navigating the fine print of the new regulations and to create a sense of community in what can be a lonely profession.

As part of its recognition of the 50th anniversary of both PRIM&R and the National Research Act, PRIM&R staff conducted interviews with its founder and first director, Joan Rachlin. The organization was grounded in Ms. Rachlin's passion for civil rights and justice. Ms. Rachlin observed that at the time of its founding, research ethics had hardly been considered in a serious way. The field of bioethics did not exist, and in fact there was very little talk of research ethics at all. PRIM&R helped usher in those conversations. PRIM&R's first tagline was "subjects' rights and freedom of inquiry." It was clear that subjects' rights came first.

Ms. Rachlin recalled that founding members of the organization were committed to building a nonprofit that would help academic and other institutions respond to the draft regulations, the National Commission's reports, and other mandates related to research review committees. It sought to help them "navigate the fine print" and address the practical implications of applying the regulations. Lori Leszczynski, the Chair of PRIM&R's Board of Directors, praised Ms. Rachlin's "tireless dedication to the education, development, and certification of professionals to help ensure research subject safety across the human and animal fields." Dr. Tillman recalled that it was at a PRIM&R conference that she herself began to embrace the profession of research ethics.

PRIM&R recognized the need for education in research ethics, as well as the need for a forum to grapple with the practical implications of the regulations. As explained by Ms. Rachlin, the primary aim of the inaugural conference was to bring people together to "share the fruits of their deliberations and discussions, to learn from each other, but also to hear what other people around the country were doing." The commitment to creating a community of support for research professionals continues today. PRIM&R has come to fill a unique role in the emerging field of research ethics education.

During PRIM&R's 2023 conference, Dr. Tillman shared her vision of the organization as one that could "increase engagement, transparency, and accountability to help build and maintain public trust in scientific research." She observed that the research landscape is ever-evolving as fast-moving technology presents opportunities and ethical challenges that

require the community not only to be responsive and sensitive to the needs of the PRIM&R community, but also to the public at large. Members of the research community must be concerned not only with restoring public trust, but also with demonstrating trustworthiness. Dr. Tillman stressed the importance of transparency and accountability in maintaining public trust. She saw PRIM&R as uniquely positioned to influence public trust around science and research by promoting transparency and accountability.

FROM RESEARCH SUBJECT TO RESEARCH PARTNER

Fifty years after the passage of the National Research Act, people are no longer seen as merely "subjects" in research but are now regarded as partners integral to the conduct of the research. This session highlights the different ways the public may be engaged in the research process to advance science and further public interests as individuals and members of a community.

1. Why I Participated in Research—A Participant's Voice

Speaker: Rey Calabrese
Former Research Participant and Current Research and Community Coordinator at Fenway Health

Rey Calabrese (they) explained that they learned about harm reduction after working in a sex shop and later, while working for Fenway Health as a recruiter of young adult research subjects. Fenway Health offered cutting-edge research opportunities with an "enormous" impact on health outcomes. Rey Calabrese participated in town halls in which they spoke as a health advocate about insurance concerns and the importance of talking to sexual partners about health issues. Calabrese helped prescreen potential subjects for a gonorrhea vaccine being tested, and became a subject themselves. They understood the serious health consequences that could ensue if the disease went untreated, and they hoped to make a small but significant impact by helping to identify a possible way of preventing the disease.

While Rey Calabrese was not personally concerned about the study's risks, they noted a number of minor inconveniences that could have deterred others. Examples included the 60-minute wait following vaccination to make sure there were no side effects and the need to keep a daily diary tracking possible symptoms. Required blood draws were also somewhat invasive.

Rey Calabrese gave prospective subjects an informed consent document to fill out in the waiting room, which helped "break the ice" in the relationship. They collaborated with community members, testers, and health navigators. They stressed the importance of finding language that is plain and affirming of gender, racial, sexual, or other identity.

Rey Calabrese highlighted a church sign they had passed that said, "motivation is fleeting, purpose is forever." Their purpose is to treat others as they would have wanted to be treated: to keep them safe and empowered, and to be empowered to empower others. They felt blessed to do this in the field of research.

2. Participants as Investigators: Participatory Action Research and Community-Led Studies

Speaker: Basaime Spate
Community Research Coordinator, Center for Justice Innovation

As a Community Research Coordinator for the Center for Justice Innovation, Mr. Spate facilitates community participation in research responsive to community needs. After the death of his parents, he grew up in the foster care system, where he suffered systematic trauma. He turned to the Bloods, a street organization, for safety, housing, food, money, and protection. Like others in the organization, he responded to outreach by Save Our Streets, which paid members to stop violence.

His work at the Center for Justice Innovation includes helping researchers use the language people use on the street so that researchers can be understood. He was also able to help researchers understand when they were being "hustled." He proved so useful to the academic team that they offered him training in research methodology so he could participate more fully in

all the phases of research. He is able to validate team members so they receive honest information from subjects and helps them craft informed consent documents that do not sound as if they are coming from a court.
Initially, Mr. Spate worked on studies of members of street organizations in Crown Heights, Brooklyn, but his work expanded to other neighborhoods. He stressed the importance of establishing relationships with potential subjects and explaining the benefits of participation. Though the incentive offered for participation in a survey was only $30, he said people were "still coming in because of who we are, our characters."

In Crown Heights, where he had established relationships, Mr. Spate said people lacked resources and experienced structural racism. "Homies were getting shot," he said, even as the team gathered data. As trust was built, people were willing to "open up on what they did and why they did it." Mr. Spate is now engaged in teaching others with similar backgrounds to his own how to do research in their neighborhoods.

3. Respecting Cultural Values: Doing Research with Indigenous Populations

Speaker: Karina L. Walters Ph.D., M.S.W.
Director of the NIH's Tribal Health Research Office (THRO)

Dr. Walters, an enrolled member of the Choctaw Nation of Oklahoma, directs an office within the NIH that collaborates with NIH Institutes and Centers as well as Tribal partners in order to "grow indigenous health and health equity through culturally credible and meaningful indigenist-driven science." She stressed that the federal government has an enforceable trust relationship with the 574 federally recognized Tribal Nations, as well as a congressional mandate to consult with Native Hawaiian organizations.

Indigenous data sovereignty, Dr. Walter explained, means that Tribal Nations have the right to govern the "collection, ownership, stewardship, management, sharing, transfer, re-use, disposition, and disposal of data collected from and about their Tribal populations." This is especially salient when these data may affect the "economic, social, cultural, and general welfare of their Tribal Nations." A movement to protect these rights coalesced over the last two decades, and a recent Executive Order has made this obligation explicit.

Dr. Walters stressed that the Common Rule 2018 Requirements stipulate that where Tribal laws and ordinances are more restrictive than the Common Rule—and they generally are—research conducted under these laws and ordinances is exempt from the 2018 Requirements. The Director noted that most Tribal laws, unlike federal rules, regard biospecimens as human subjects, even when de-identified. Some Tribes may require that biological material collected from a subject follow the person to the afterworld. It is important to create legacy plans that protect cultural rights. Not only individuals, but the Tribes themselves must give their informed consent for study participation. Ownership and authority over data rests with the Tribal Nation, whose sovereignty and governance must be respected.

4. Listening to the People: Community Ethics Review Boards

Speaker: Ella Greene-Moton
Member of a Community Ethics Board in Flint, Michigan, and President of the American Public Health Association

Ms. Greene-Moton spoke as the first community-level, non-degreed person to be elected President of the American Public Health Association (APHA) in its 150-year history. She explained the role of community ethics boards as a source of feedback and advice for researchers on the needs, perspectives, and values of the communities in which they propose to do research.

The Community Ethics Board in Flint, Michigan, on which Ms. Greene-Moton serves, was founded in 2015 by Kent Key of the Michigan State University College of Human Medicine and is composed of area volunteers. The Board examines potential and actual research proposals through the lens of community ethics and helps establish an ongoing dialogue between researchers and community members. The Board provides a safety net for the community, ensuring that research is morally

sound and beneficial to them. Ms. Greene-Moton stressed that the community must be engaged and informed throughout the research process.

Members of the Community Ethics Review Board are trained to review proposals and receive a modest stipend for their services. Their assistance and guidance are available from project conceptualization to completion as requested by the project leads. Concerns about the research can be heard and addressed through the Board's efforts. Ms. Greene-Moton emphasized the importance of disseminating research findings to the community and ensuring they are available for community use.

5. Engaging the Community in Research: The Insight of an Investigator

Speaker: Sergio Aguilar-Gaxiola, M.D., Ph.D.
Founding Director of the Center for Reducing Health Disparities at UC Davis Health and the Director of the Community Engagement Program of the UCD Clinical Translational Science Center (CTSC)

Dr. Aguilar-Gaxiola echoed other speakers in stressing the importance of trust and trustworthiness in the conduct of responsible research. Meaningful community engagement is a critical element of research that seeks to improve the health (including mental health) of communities and to advance equity in both physical and mental health.

A Centers for Disease Control (CDC) report, Principles of Community Engagement, 3rd edition, articulates 10 essential principles to accomplishing this aim. These include:

1. Be clear about the population and communities to be engaged and the goals of the effort.
2. Know the community, including its norms, history, and experience with engagement efforts.
3. Build trust and relationships and get commitments from formal and informal leadership.
4. Collective self-determination is the responsibility and right of all community members.
5. Partnering with the community is necessary to create change and improve health.
6. Recognize and respect community cultures and other factors affecting diversity in designing and implementing approaches.
7. Sustainability results from mobilizing community assets and developing capacities and resources.
8. Be prepared to release control of actions to the community and be flexible enough to meet its changing needs.
9. Community collaboration requires long-term commitment.
10. Trustworthiness is fundamental to sustainable community engagement and for advancing health equity.

Principle 10, Dr. Aguilar-Gaziola stressed, deserves particular attention. Trustworthiness is essential to forming effective partnerships and, over time, will deepen commitment through building relationships based on empathy, honesty, respect, and humility. Partnerships should be built around deliberative means of engagement, and communication must be bidirectional. Researchers should listen attentively to what matters to communities and make sure their research plans take this input into account.

The National Academy of Medicine's Leadership Forum, in concert with the Robert Wood Johnson Foundation and the California Health Care Foundation, seeks to "identify concepts and metrics that can best assess the extent, process, and impact of community engagement." A conceptual model for assessing community engagement developed by the Forum highlights strengthened partnerships and alliances, expanded knowledge, improved health and health care programs and policies, and thriving communities as indicators of systems of health that have been transformed through successful community engagement.

Dr. Aguilar-Gaxiola identified three areas in which challenges must be addressed to accomplish the important goals of community engagement:

- **People.** How are we going to manage the simultaneous research, clinical, and educational challenges when those who do meaningful community-engaged research and who can bridge the cultural divides are few?
- **Sustainability.** How will the efforts be sustained?
- **Metrics.** What outcomes should we be measuring? What are the measures that matter to communities?

The speaker closed by highlighting several key lessons he has learned over 40 years of building and maintaining community–academic partnerships. These include:

- Multistakeholder community partnerships are required in order to improve health/mental health of communities with which we work.
- Use a health/mental health equity lens.
- Listen attentively to all and treat partners with dignity and respect.
- Review local data on health/mental health outcomes in local communities, connect the dots, and look for what is missing. The speaker noted that quite a bit of data is often available.
- While researchers' focus is often on community deficits, Dr. Aguilar-Gaxiola encouraged them to look actively for community assets, strengths, and resilience. Learn about them and use them!
- Design and implement for sustainability right from the beginning.
- Don't overplan, but learn and adapt as you go.
- Build trust and demonstrate trustworthiness.

CONTEMPLATING THE FUTURE

Speakers in this panel discussion explored the potential impact of scientific advances in the coming decades, the challenges they may present to the notion of "human research protection," the stress they may present on public trust, and what the scientific community can do to prepare. Both opportunities and challenges, such as those posed by Artificial Intelligence (AI), are considered.

Moderator:
Laura Ruse Brosch, R.N., Ph.D., COL, AN, USA (ret)
Assistant Vice President for Research Initiatives and Compliance, Office of the Vice President for Research, Uniformed Services University of the Health Sciences

Panelists:

- Misha Angrist, Ph.D., M.F.A.
  Associate Professor of the Practice, Social Science Research Institute; Senior Fellow, Duke Initiative for Science & Society; Visiting Associate Professor of the Practice, Sanford School of Public Policy
- Jodi Halpern, M.D., Ph.D.
  Chancellor's Chair and Professor of Bioethics, UC Berkeley
- Lee McIntyre, Ph.D.
  Research Fellow, Center for Philosophy and History of Science, Boston University; Senior Advisor for Public Trust in Science at the Aspen Institute
- Aaron F. Mertz, Ph.D.
  Director, Science and Society, Aspen Institute

As moderator, Dr. Brosch began by inviting panelists to explore the potential impact of scientific advances in the coming decades:

- **What are some of the revolutionary scientific developments that we can expect to see in biomedicine and health in the coming decades? What ethical considerations do these potential benefits and harms raise for you?**

Dr. Halpern highlighted the rapid rise of AI, which provides powerful research tools but also challenges the research community to think outside the box and consider how these tools are employed. For example, ways of reading our brains and converting our thoughts to speech are on the horizon. As helpful as this might be to stroke patients, the technology can also be used for surveillance. The ethics surrounding genome editing and neurotechnology also present multiple challenges.

A second area of concern is the increased influence of direct-to-consumer health interventions. AI has made possible a profitable business in artificial companions and therapists based on young people's need for companionship. Many of them spend 8 to 10 hours a day on social media already, and this new use of generative AI with potential addictive properties caters to those who are lonely, depressed, or anxious. There is no regulatory model to oversee this kind of experience.

Dr. Brosch then turned to the challenges such innovations may pose to the notion of "human research protections."

- **Research ethics has traditionally focused on protecting individual autonomy and minimizing harms to individuals. What have we learned about the strengths and weaknesses of the IRB system over the last 50 years?**

Dr. Angrist reflected that the IRB system is "pretty good" at preventing egregious violations of justice like the Tuskegee study most of the time. However, in accomplishing this, an adversarial relationship has developed between investigators and IRBs, often seen as "ethics police." This has led to a culture of compliance rather than conscience. Also, an unintended consequence of the regulation's efforts to protect vulnerable populations is that some investigators find it too difficult to work with them. For example, they may find it too expensive to hire translators.

Dr. Brosch invited panelists' reflections on public trust in science.

- **What is your sense of public trust for science today, perhaps limited to biomedical and health research? How do you think it's changed over the last 50 years?**

Dr. Mertz said that science has suffered from a failure to send a cohesive message to diverse audiences. Consistent and updated guidance in health crises such as the COVID 19 pandemic is critical, but scientists have been less than successful at this, eroding trust.

While scientific research has brought countless benefits, it also brought us Agent Orange, the meltdown at Three-Mile Island, and thalidomide. Often, harms are borne by the same communities. As the public weighs scientific expertise versus policy makers' opinions, scientists must work from a position of cultural humility and strive for inclusion.

Dr. McIntyre noted that public trust in science and scientists declined significantly following the COVID-19 pandemic, although some would point out it has declined less than trust in public institutions such as Congress. There is an enormous partisan split—20 percentage points difference between Republicans and Democrats—in public decline in confidence in science. However, Dr. McIntyre felt data were lacking on the specific areas in which scientists have and do not have credibility with certain populations.

Fifty years ago, at the time of the moon launch, people generally trusted science even if they didn't understand it. A steady diet of lies has let to science denialism, causing people to distrust people who do not believe the same falsehoods.

Given the current state of affairs, Dr. Brosch asked panelists to reflect on what the scientific community should be doing to regain the public trust essential for successful research and prepare for future challenges.

- **What can the scientific community do to prepare for the future and win public trust?**

Dr. McIntyre observed that many people simply do not know any scientists. Face-to-face conversations can help improve credibility. He advised researchers to seek out conversations and lean into the question of uncertainty. It is important not to give people the impression that things are proven when more research may yield a different conclusion, as people will then feel misled and become less inclined to trust in the future.

Dr. McIntyre said he believed that former Director of the National Institute of Allergy and Infectious Diseases Dr. Anthony Fauci did not make the best choice in communication strategy when he discouraged the use of masks at the outset of the pandemic. It could not have hurt to wear a mask, Dr. McIntyre pointed out, even if the practice's efficacy against COVID 19

had not yet been shown. If the message had included asking people to reserve N95 masks for health care providers, trust might not have declined so precipitously.

Dr. Mertz agreed that effective communication around changes in science is critical. It is important to acknowledge scientific uncertainty. Encouraging the inclusion, participation, and engagement in science by diverse groups is also important, since many of them see scientists as elite, straight, conservative white males who are different from themselves. Scientists need to make themselves accessible and build personal connections. To accomplish this, he would like to see communication skills incorporated in scientists' academic preparation.

The education of scientists should also encompass public accountability, Dr. Halpern stressed. Not only do scientists need preparation for public engagement, but they also need to understand their ethical obligations. Dr. Halpern described the recent launch of the UC Berkeley Kavli Center for Ethics, Science, and the Public to engage scientists in ethics and public engagement early in their scientific careers.

Dr. Angrist noted that one way the disconnect between "civilians" and scientists is revealed is in the scarcity of subjects interested in research participation. Some soul searching is needed on the part of investigators to determine how to make participation in science less scary, less exhausting, and more attractive to patients and their caregivers. What can we do to incentivize participation in research beyond framing it as a nice thing to do and, as some bioethicists have proclaimed, "a moral obligation"? As other speakers had observed, partnering with participants rather than using them as a means to end is an important part of the solution.

In closing, Dr. Brosch invited panelists' views on areas in which the Common Rule may require further revisions. She reminded listeners that the Rule applies only the federal research.

- **What changes to the Common Rule do you think might be needed to accommodate future directions in research?**

Dr. Angrist noted that an arduous 7-year process was needed to accomplish the most recent revisions to the Common Rule. Rather than focusing on revising the Common Rule, Dr. Angrist highlighted the possibility of doing more science "from the bottom up." He pointed to the example of Dana Lewis, who created an artificial pancreas with an open source code to meet the needs of people with Type 1 diabetes. While this accomplishment made her a pariah in the eyes of many medical device companies and endocrinologists, her breakthrough was based on a keen understanding of a need and resulted in a significant benefit to diabetic patients.

Dr. Mertz highlighted a forthcoming feature-length film, Six Degrees from Science, which is intended to shed light on science research and education. It portrays the trials and tribulations that go into scientific careers and attempts to make people aware of how science has contributed to their everyday lives. Through entertaining storytelling, the film is intended to educate the public on how discoveries are made. Release is scheduled for early 2025.

In closing, Dr. Lau thanked all panelists and speakers. She underlined the consistent message that engagement with the public and effective communication are critical to the success of scientific endeavors. In improving credibility with the public and greater participation in research, empathy, honesty, and respect from the scientific community are essential.

OASH

Office for
Human Research
Protections