A MATCH MADE IN SCIENCE

INTEGRATING BIOETHICS AND BIOMEDICAL RESEARCH

July 20, 2021
1-4 PM ET

NIH

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SUMMARY
"A Match Made in Science: Integrating Bioethics and Biomedical Research"

Overview

The NIH Office of Science Policy hosted a three-hour virtual symposium entitled "A Match Made in Science: Integrating Bioethics and Biomedical Research" on July 20, 2021. Invited biomedical researchers, bioethicists, and NIH staff participated in panels highlighting the integral role bioethics plays in advancing science and strategies for fostering collaboration between bioethicists and biomedical researchers. The symposium was available live to the public via the NIH VideoCast website, and a recorded version of the event is available at the following link.

Opening Remarks

In his opening remarks, NIH Director Dr. Francis S. Collins emphasized NIH's commitment to bioethics across the agency, noting that integrating bioethics improves NIH research while reinforcing NIH's responsibilities as an ethical steward of biomedical research. Dr. Collins reflected on the incorporation of bioethics into key NIH initiatives, detailing how bioethics informed the selection of an anonymous reference sequence for the human genome (as opposed to one associated with an identified individual) and how NIH's Department of Bioethics consulted on issues related to challenge trials, the inclusion of pregnant individuals and children, and diversity in COVID vaccine trials.

Panels

The symposium featured two panel sessions. Speakers in the first session, "Strengthening Outcomes: The Value Bioethics Brings to Biomedical Research," shared examples of how integrating bioethics into biomedical research has strengthened their research. The second session, "Finding the Win/Win: Practical Advice for Bioethicists and Biomedical Researchers" featured a moderated discussion exploring mechanisms and incentives for initiating and sustaining successful collaborations between bioethicists and biomedical researchers.

Themes

Several overarching themes emerged from the symposium.

Integrating bioethics with biomedical research can help surface and resolve research tensions

Balancing respect for research participants (e.g., autonomy, beneficence, and privacy) can appear at odds with advancing medical care and science. Bioethicists included as part of research teams can help identify ethical tensions and provide guidance on how to proceed. An example presented at the Symposium illustrated how, when a learning healthcare system was being developed, bioethicists involved in the project recommended that the researchers work with patients to understand their preferences when developing procedures for notification, consent, data use, and governance. This input enabled the researchers to clarify the boundaries between clinical practice and research, enhancing the study design and helping ensure that barriers to participation were overcome. For this study and others, bioethics can play a critical role in enabling research to move forward in a way that is consistent with stakeholder and societal values, empowers individuals to choose to engage and participate in research, and improves the research.

Bioethics integration can facilitate trust in science

The inclusion of bioethicists on a research team can ensure that practices that could erode public trust in the study – and in science more broadly – are anticipated and avoided. For example, when bioethicists work with biomedical researchers to assess stakeholder perspectives and include these perspectives in

the development and deployment of new or emerging scientific methods or technologies, the impact of research can be strengthened as outcomes are grounded in a foundation of trust. Enhanced trust in the scientific enterprise can foster engagement in science, including among individuals from communities historically underserved by biomedicine, leading to increased participation in research and, thus, more impactful results.

Bioethics has relevance for biomedical research, even when connections are not readily apparent

Bioethics is needed for rapidly evolving technologies to succeed, particularly when the research for those technologies occurs across geographic regions or communities. This need is not always apparent to biomedical researchers, who may assume that, because they design technologies to be helpful in resolving societal or healthcare system issues, the technologies do not raise ethical questions. Discussion around the development of a highly portable, cloud-enabled MRI highlighted this point, as a biomedical researcher who developed the technology noted that he initially believed the technology would be necessarily beneficial. After connecting with a neuroethicist, however, the team began a research partnership to systematically study the ethical, legal, and social implications of use of this new MRI technology with diverse populations in field settings, to ensure that the technology would reach and benefit diverse communities.

Mutual willingness to work together is required for successful collaborations between bioethicists and biomedical researchers

Being "radically collaborative" – i.e., being proactive in reaching out to colleagues and generous with time and ideas – is important in establishing cross-disciplinary collaborations that strengthen science. This approach transcends traditional 'silo-ing' in academia. It was noted that it can take time to develop meaningful professional relationships, particularly among individuals with different disciplinary backgrounds. Humility and willingness to listen are key to developing strong collaborations. Additionally, it is important to be creative when looking for opportunities to collaborate. For example, embedding a bioethics aim within a biomedical research project, or putting together an administrative supplement to add a bioethics component to a biomedical research project, are effective ways to foster collaboration.

To facilitate collaborations between bioethicists and biomedical researchers, more sustainable funding mechanisms are needed

Thoughtful leadership buy-in and institutional structures are essential for successful bioethics integration into biomedical research. Leadership at academic research and medical institutions can play an important role in supporting collaborations between bioethicists and biomedical researchers by reducing and eliminating barriers and incentivizing a team approach to science. Sustainable funding mechanisms are also needed to support opportunities that enable collaboration between bioethicists and biomedical researchers.

Conclusion

Bioethics engagement over the lifecycle of biomedical research projects can enhance the conduct and output of research, ensuring better science, increased inclusion of participant, stakeholder, and societal values, and engendering greater trust in the biomedical research enterprise. Bioethicists, biomedical researchers, institutions, and funders all have an important role to play in building the relationships and structures that can enable bioethicists and biomedical researchers to collaboratively advance science.

NATIONAL INSTITUTES OF HEALTH

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https://videocast.nih.gov/watch=42402

Moral principles evolve over time in society and our understanding of the world around us changes with each new discovery. To enable the rapid translation of research discoveries into practice, good science and robust ethics must go hand in hand. Consideration of ethical aspects of research in tandem with the research process itself offers many benefits, not only for society but for the research itself. The goals of this symposium are to highlight the integral role that bioethics plays in advancing science and to discuss strategies for fostering collaboration between bioethicists and biomedical researchers.

1:00 PM **Welcome and Overview of Symposium Goals**
Francis S. Collins, MD, PhD – Director, National Institutes of Health (NIH)

1:10 PM **Strengthening Outcomes: The Value Bioethics Brings to Biomedical Research**
Researchers and bioethicists come together to provide concrete examples of how successful integration of bioethics into biomedical research can strengthen study designs, mitigate future hurdles, and inspire future research inquiries.

Moderator: Khara Ramos, PhD – Director, Neuroethics Program, National Institute of Neurological Disorders and Stroke, NIH

Speakers:

- **Integrating Bioethics into the Design of Learning Health Systems**
  Reshma Jagsi, MD, DPhil – Newman Family Professor, Director of the Center for Bioethics and Social Sciences in Medicine, and Deputy Chair of the Department of Radiation Oncology, University of Michigan

- **Creating an Ethical Framework for Clinical Implementation of Suicide Risk Prediction Models**
  Bobbi Jo Yarborough, PsyD – Senior Investigator, Kaiser Permanente Northwest Center for Health Research

- **Evidence-Based Models for Adolescent Engagement in Research and Care in Global Settings**
  Grace John-Stewart, PhD – Professor, Departments of Global Health, Epidemiology, Medicine, and Pediatrics, University of Washington

Seema K. Shah, JD – the Founder's Board Professor of Medical Ethics and Director of Research Ethics at Lurie Children's Hospital, and Associate Professor of Pediatrics at Northwestern University

2:30 PM **Finding the Win/Win: Practical Advice for Bioethicists and Biomedical Researchers**
Researchers and bioethicists come together to explore best practices and identify potential challenges in establishing successful collaborations, including identifying mechanisms for partnership and strategies for aligning incentives.

Moderator: Charlisse Caga-anan, JD, MA – Program Director, Division of Cancer Control and Population Sciences, National Cancer Institute, NIH

Panelists:

- **The Journey to Discovering Bioethics: A Biomedical Researcher's Perspective**
  Michael Garwood, PhD – Professor and Associate Director, Center for Magnetic Resonance Research, University of Minnesota

- **Being Radically Collaborative to Advance Science: A Bioethicist's Perspective**
  Jennifer K. Wagner, JD, PhD – Assistant Professor, Center for Translational Bioethics and Health Care Policy and Associate Director of Bioethics Research, Geisinger

3:40 PM **Summary of Sessions**
Khara Ramos, PhD – Director, Neuroethics Program, National Institute of Neurological Disorders and Stroke, NIH
Charlisse Caga-anan, JD, MA – Program Director, Division of Cancer Control and Population Sciences, National Cancer Institute, NIH

3:55 PM **Concluding Remarks**
Lyric Jorgenson, PhD – Acting Associate Director for Science Policy, NIH

4:00 PM **Adjourn**

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Speaker Bios

Charlisse Caga-anan, JD, MA is a Program Director at the National Cancer Institute (NCI) Division of Cancer Control and Population Sciences (DCCPS), in the Epidemiology and Genomics Research Program (EGRP). In this role, she works to grow NCI's portfolio of bioethics research grants and is the NCI scientific contact for research on the ethical, legal, and social implications (ELSI) of genomics, and for bioethics research relevant to cancer. Additionally, she implements the NIH Genomic Data Sharing (GDS) Policy by serving as the DCCPS Genomic Program Administrator. She was formerly the Chair of the extramural NCI Data Access Committee. Prior to joining NIH, she was a Postdoctoral Scholar at the Center for Genetic Research Ethics and Law, a National Human Genome Research Institute (NHGRI)-funded Center for Excellence in ELSI Research. She also completed the Cleveland Fellowship in Advanced Bioethics. She holds a JD from the University of Minnesota and an MA in Bioethics from Case Western Reserve University.

Francis S. Collins, MD, PhD was appointed the 16th Director of the NIH by President Barack Obama and confirmed by the Senate. He was sworn in on August 17, 2009. In 2017, President Donald Trump asked Dr. Collins to continue to serve as the NIH Director. President Joe Biden did the same in 2021. Dr. Collins is the only Presidentially appointed NIH Director to serve more than one administration. In this role, Dr. Collins oversees the work of the largest supporter of biomedical research in the world, spanning the spectrum from basic to clinical research. Dr. Collins is a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the international Human Genome Project, which culminated in April 2003 with the completion of a finished sequence of the human DNA instruction book. He served as director of NHGRI at NIH from 1993-2008. Dr. Collins is an elected member of both the National Academy of Medicine and the National Academy of Sciences, was awarded the Presidential Medal of Freedom in November 2007, and received the National Medal of Science in 2009. In 2020, he was elected as a Foreign Member of the Royal Society (UK) and was also named the 50th winner of the Templeton Prize, which celebrates scientific and spiritual curiosity.

Michael Garwood, PhD is a Professor and the Associate Director of the Center for Magnetic Resonance Research at the University of Minnesota. He leads the pursuit of a next-generation neuroimaging platform based on magnetic resonance imaging (MRI) that will provide new frontiers for human brain research, particularly in terms of better understanding human behavior and motor coordination. He conceived of the novel silent MRI technique known as sweep imaging with Fourier transformation (SWIFT), and together with co-investigators he showed how it can measure brain activity with no echo (i.e., non-BOLD fMRI). In addition, his group has developed spatiotemporal encoding to overcome a significant limitation of MRI, which is its intolerance of magnetic field inhomogeneity. This discovery is key to establishing portable, high-field MRI scanners for neuroscience research, and ultimately, for clinical use, in remote and resource-limited settings.

Reshma Jagsi, MD, DPhil is Newman Family Professor and Deputy Chair in the Department of Radiation Oncology and Director of the Center for Bioethics and Social Sciences in Medicine at the University of Michigan. Dr. Jagsi is an internationally recognized clinical trialist and health services researcher, whose research focuses on improving the quality of care received by breast cancer patients, as well as issues of bioethics and gender equity in academic medicine. She has served on the Steering Committee of the Association of American Medical College's (AAMC's) Group on Women in Medicine in Science and now serves on the Board of Directors of the American Society of Clinical Oncology and the NCI's BOLD task force on locoregional management of breast cancer. Her work is frequently featured in the popular media, including coverage by the New York Times, Wall Street Journal, Washington Post, National Public Radio, and national network nightly news. She has delivered invited talks at over 50 institutions and professional societies, including the AAMC, the NIH, and the National Academy of Medicine and National Academy of Sciences. She has been elected to the American Society of Clinical Investigation and is an elected fellow of the American Society for Radiation Oncology, American Society of Clinical Oncology, American Association for Women in Radiology, and the Hastings Center. Additionally, she received the Leadership Award of AAMC's Group on Women in Medicine and Science.

Grace John-Stewart, MD, PhD is a Professor in the Departments of Global Health, Medicine, Epidemiology and Pediatrics at the University of Washington (UW). Her research focuses on advancing HIV prevention and treatment in women, adolescents and children, as part of a collaborative research project in Kenya. This work has included clinical trials, molecular epidemiology, implementation science, and large-scale evaluations. She received the Elizabeth Glaser Pediatrics AIDS Foundation Scientist Award and in 2021, the American Society of Schools of Public Health Research Excellence Award for outstanding research that has public health impact. Her research has been disseminated in >400 publications. She was the Founding Director and is currently Co-Director of the UW Center for Global Health of Women, Adolescents and Children and is an Associate Director of the UW Center for AIDS Research.

Lyric Jorgenson, PhD is the Acting Associate Director for Science Policy and the Acting Director of the Office of Science Policy at the NIH. In this position, she provides senior leadership in the development and oversight of cross-cutting biomedical research policies and programs considered to be of high-priority to NIH and the United States Government. Prior to this role, she served in numerous roles across the agency, including Deputy Director of the Office of Science Policy, and has led the development of numerous high impact science and policy initiatives such as the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the National Center for Advancing Translational Sciences (NCATS). Dr. Jorgenson also served as the Deputy Executive Director of the White House Cancer Moonshot Task Force in the Office of the Vice President in the Obama administration, where she directed and coordinated cancer-related activities across the Federal government and worked to leverage investments across sectors to dramatically accelerate progress in cancer prevention.

Khara Ramos, PhD serves as Director of the Neuroethics Program and Chief of the Neuroscience Content and Strategy Branch in the Office of Neuroscience Communications and Engagement (ONCE) at the National Institute of Neurological Disorders and Stroke (NINDS) at NIH. She leads neuroethics activities for NINDS and the NIH BRAIN Initiative, serves as co-lead of the trans-NIH BRAIN neuroethics project team, and co-chairs the trans-NIH Coordinating Committee for Bioethics Research and Training. In her role within ONCE, she oversees strategic coordination and communications planning for NINDS-supported neuroscience research, and curation of expert information about this research. She also oversees coordination of the NIH BRAIN Initiative's Neuroethics Working Group and Multi-Council

Working Group. Previously, Dr. Ramos worked as Special Assistant to the Deputy Director of National Institute of Dental and Craniofacial Research (NIDCR), where she served as point person on high profile projects for NIDCR and provided support to the NIDCR Office of the Director regarding policy analysis, communications, program oversight, evaluation activities, strategic planning, and project coordination. She originally moved from academia to federal service via the American Association for the Advancement of Science - Science and Technology Policy Fellowship Program, following a post-doctoral fellowship at the University of Colorado, Boulder, where she studied the role of non-neuronal cells of the central nervous system in chronic pain states and in opioid-induced central sensitization. Dr. Ramos holds a PhD in neurosciences from the University of California, San Diego, and a bachelor's degree in Symbolic Systems from Stanford University.

Seema K. Shah, JD is the Founder's Board Professor of Medical Ethics and the Director of Research Ethics at Lurie Children's Hospital. She is also an Associate Professor of Pediatrics at Northwestern University Feinberg School of Medicine, with a courtesy appointment at Northwestern's Pritzker School of Law. Professor Shah is an international expert in the fields of pediatrics and global health research ethics, as well as on legal and ethical issues in the determination of death. She has published more than 70 articles in the medical, bioethics, and legal literatures and is the co-author of a book on Research Ethics Consultation. She has lectured on these topics around the world and had numerous media mentions and appearances, including in the Wall Street Journal, the New York Times, and PBS NewsHour. Professor Shah attended Stanford University for her undergraduate and law degrees and completed a fellowship in bioethics at the NIH Clinical Center. She clerked in federal district court in Sacramento, California. Professor Shah was previously on faculty at the University of Washington/Seattle Children's Hospital and at the NIH Clinical Center Department of Bioethics. Finally, Professor Shah has a distinguished record of service, including chairing an NIH committee on ethical considerations in conducting Zika virus human challenge trials and serving as an expert member of a World Health Organization working group to develop key criteria for human challenge trials to address COVID-19 and beyond.

Jennifer K. Wagner, JD, PhD is currently the Associate Director for Bioethics Research at Geisinger's Center for Translational Bioethics and Health Care Policy and, effective August 2021, will be an Assistant Professor of Law, Policy, and Engineering at Penn State University. Her research efforts are driven by her commitment to the international human right of everyone "to participate...and to share in scientific advancement and its benefits" (Universal Declaration of Human Rights, Article 27). Working primarily in two technical domains - genetics and mobile health technologies - Dr. Wagner conducts multidisciplinary research in four highly interrelated topical areas: (1) biases and discrimination (including race, ancestry, and appearance-based discrimination); (2) vulnerable populations (including, e.g., athletes and the "data rich" and "data poor"); (3) patient/participant/consumer-centered design and engagement; and (4) law and policy (including separation of powers, privacy, and data justice). She has contributed to Geisinger's MyCode Community Health Initiative and the NIH All of Us Research Program. Dr. Wagner also has served as a contributing editor for the Genomics Law Report, co-chair of the ethics committee for the American Association of Physical Anthropologists, chair of the Social Issues Committee for the American Society of Human Genetics, member of the Pennsylvania Bar Association's Cybersecurity and Data Privacy Committee, associate editor for Human Genetics and Genomics Advances, and member of the Scientific Advisory Board for Sage Bionetworks. Her ELSI research has been funded by the NHGRI, NCI, NIDCR, and NIH Office of the Director and has been cited by the Supreme Court of the United States.

Bobbi Jo Yarborough, PsyD is a Senior Investigator at Kaiser Permanente's Center for Health Research. As a clinical psychologist and health services researcher, she works to improve care and outcomes among individuals with serious mental illnesses and/or substance use disorders. Dr. Yarborough has been the principal investigator or co-investigator on more than a dozen research contracts or grants funded by the NIH and FDA. Her portfolio includes studies of adolescent and adult depression treatment, suicide prevention, eating disorders treatment, lifestyle change among people with serious mental illnesses, first-episode psychosis, recovery from serious mental illnesses, dual recovery among people with mental illnesses and substance problems, opioid use and associated risks, and preferences for opioid agonist treatment. Dr. Yarborough is a member of the Mental Health Research Network, funded by NIMH, and the site principal investigator for the Health Systems Node of the National Institute on Drug Abuse (NIDA) Clinical Trials Network.