The sixth of 10 listening sessions to gather feedback on the proposed Advanced Research Projects Agency for Health (ARPA-H) was held virtually on August 3, 2021. Advocates for research on diabetes, digestive disorders, and kidney disease; child and maternal health; and complementary and integrative medicine shared their opinions. The National Institutes of Health (NIH) is working closely with the White House Office of Science and Technology Policy (OSTP) to establish ARPA-H to focus on ambitious and innovative projects that will shape the future of health and medicine for all Americans.
Participants

White House Office of Science and Technology Policy (OSTP)
Tara A. Schwetz, Ph.D., Assistant Director for Biomedical Science Initiatives

National Institutes of Health (NIH)
Francis S. Collins, M.D., Ph.D., Director
Alison Cernich, Ph.D., Deputy Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Helene Langevin, M.D., Director, National Center for Complementary and Integrative Health (NCCIH)
Griffin P. Rodgers, M.D., MACP, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

Stakeholders
Brian Berman, M.D., Professor Emeritus, Department of Family and Community Medicine, University of Maryland School of Medicine, Baltimore, MD; President, Institute for Integrative Health, Baltimore, MD
Michael D. Cabana, M.D., M.P.H., Professor, Department of Pediatrics, Michael I. Cohen University Chair, Department of Pediatrics, Albert Einstein College of Medicine, New York, NY; Chair, Committee on Pediatric Research, American Academy of Pediatrics (AAP), Itasca, IL
James Graham, Ph.D., D.C., M.S., Director, Center for Community Partnerships; Professor, Department of Occupational Therapy, Colorado State University, Fort Collins, CO; American Congress of Rehabilitation Medicine (ACRM), Reston, VA
Lindsey Horan, M.A., Chief Advocacy Officer, Society for Women’s Health Research (SWHR), Washington, DC
Benjamin Kligler, M.D., M.P.H., Executive Director, Office of Patient Centered Care and Cultural Transformation, U.S. Department of Veterans Affairs (VA), Washington, DC
M. Bishr Omary, M.D., Ph.D., AGAF, Adjunct Professor, Molecular & Integrative Physiology, Adjunct Professor, Internal Medicine, Division of Gastroenterology, University of Michigan Medical School, Ann Arbor, MI; Past President, American Gastroenterological Association (AGA), Bethesda, MD
Melissa West, Senior Director, Strategic Relations and Patient Engagement, American Society of Nephrology (ASN), Washington, DC
Carol H. Wysham, M.D., Clinical Professor of Medicine, University of Washington School of Medicine, Spokane, WA; President, Endocrine Society, Washington, DC
Meeting Summary

Welcome and Opening Remarks
Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health (NIH)
Tara A. Schwetz, Ph.D., Assistant Director for Biomedical Science Initiatives, White House Office of Science and Technology Policy (OSTP)
Griffin P. Rodgers, M.D., MACP, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Alison Cernich, Ph.D., Deputy Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
Helene Langevin, M.D., Director, National Center for Complementary and Integrative Health (NCCIH)

Dr. Collins welcomed participants and attendees to the sixth of 10 listening sessions to gather feedback on the proposed Advanced Research Projects Agency for Health (ARPA-H). NIH is working closely with OSTP on ARPA-H, which is a high priority for the Biden administration. ARPA-H is designed to catalyze ambitious ideas and approaches that will shape the future of health and medicine for all Americans. The new agency, which will follow the Defense Advanced Research Projects Agency (DARPA) model, will focus on high-risk, high-reward projects and will be guided by visionary project managers. ARPA-H will recruit researchers who might otherwise not apply to NIH for support, and its projects will be driven by clearly defined milestones. OSTP and NIH wish to gather opinions from stakeholders, who will play a critical role in the establishment and success of ARPA-H. The 10 listening sessions will focus on specific research areas and will involve NIH Institute and Center (IC) directors who represent those areas.

Dr. Schwetz said that ARPA-H will strive to be transformative for biomedical research. The United States has a strong biomedical research ecosystem that is supported by NIH-funded research. Results from these research studies have informed the pharmaceutical industry in its development of treatments for several conditions. However, the current system has some gaps between traditional fundamental research and industry. ARPA-H will help provide a new lens and a mechanism through which to support exciting biomedical research that can improve human health. Such ambitious and cutting-edge research requires a novel funding approach: the ARPA model, which has been used in other areas of science. In ARPA-H, OSTP and NIH aim to create a distinct entity whose leadership will have the autonomy and resources to tackle some of the biggest challenges facing human health.

Dr. Rodgers said that NIDDK has a broad research responsibility that includes some of the most common, debilitating, and costly conditions affecting Americans. While NIDDK research is actively looking at ways to reduce the burden of these conditions, ARPA-H could complement this work by taking on visionary research with the potential to revolutionize care for chronic diseases. As is the case for much of NIH, many of the diseases in NIDDK’s mission have a disparate impact on Americans from minority groups and on people who have lower incomes. It is critical to apply ARPA-H’s resources in ways that move the nation toward health equity.

Dr. Cernich said that NICHD leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities
for all. During its recent strategic planning process, NICHD considered a number of aspirational goals that it could pursue in partnership with other ICs for a broad impact. ARPA-H could help accelerate some of these goals and address health disparities. ARPA-H could also help NICHD establish collaborations with new partners to advance research into endometriosis, maternal mortality, limb regeneration and repair, and the impact of digital media on child development.

Dr. Langevin said that ARPA-H will aim to develop transformative tools and platforms for the benefit of patients, a goal that is well aligned with NCCIH’s focus on whole person health. Whole person health involves empowering individuals to improve their health in multiple interconnected domains. ARPA-H can catalyze this vision by harnessing and integrating information from all areas of life rather than focusing on one disease at a time. ARPA-H could help develop technology that will lead to a true learning health care system that would empower the patient while providing comprehensive data that could be deidentified for research purposes. NIH by itself cannot fix the U.S. health care system; ARPA-H could help motivate the private sector to help tackle the most complex and pressing problems that are dragging down the health of the nation.

**Comments from Invited Stakeholders**

M. Bishr Omary, M.D., Ph.D., AGAF, Adjunct Professor, Molecular & Integrative Physiology, Adjunct Professor, Internal Medicine, Division of Gastroenterology, University of Michigan Medical School, Ann Arbor, MI; Past President, American Gastroenterological Association (AGA), Bethesda, MD

Melissa West, Senior Director, Strategic Relations and Patient Engagement, American Society of Nephrology (ASN), Washington, DC

Carol H. Wysham, M.D., Clinical Professor of Medicine, University of Washington School of Medicine, Spokane, WA; President, Endocrine Society, Washington, DC

James Graham, Ph.D., D.C., M.S., Director, Center for Community Partnerships; Professor, Department of Occupational Therapy, Colorado State University, Fort Collins, CO; American Congress of Rehabilitation Medicine (ACRM), Reston, VA

Lindsey Horan, M.A., Chief Advocacy Officer, Society for Women’s Health Research (SWHR), Washington, DC

Michael D. Cabana, M.D., M.P.H., Professor, Department of Pediatrics, Michael I. Cohen University Chair, Department of Pediatrics, Albert Einstein College of Medicine, New York, NY; Chair, Committee on Pediatric Research, American Academy of Pediatrics (AAP), Itasca, IL

Brian Berman, M.D., Professor Emeritus, Department of Family and Community Medicine, University of Maryland School of Medicine, Baltimore, MD; President, Institute for Integrative Health, Baltimore, MD

Benjamin Kligler, M.D., M.P.H., Executive Director, Office of Patient Centered Care and Cultural Transformation, U.S. Department of Veterans Affairs (VA), Washington, DC

Dr. Omary said that gastrointestinal diseases contribute significantly to health care costs and to mortality worldwide. AGA will wholeheartedly support the creation of ARPA-H because the agency will drive transformational innovation and breakthroughs in health-related research.
AGA recommends that ARPA-H leadership aim for transparency in its project selection criteria and decision making processes. ARPA-H needs to prioritize collaborations with stakeholders to identify areas of focus to help the agency meet its goals and maximize the impact of its projects. AGA recommends that decision makers adopt similar approaches to DARPA’s and that ARPA-H be funded at a substantial level from its inception to ensure that programs and initiatives have the necessary support. ARPA-H funding should not affect the funding levels of other federally supported research efforts. Also, the principles used to set ARPA-H priorities should incorporate a definition of need and aim to address health inequities. ARPA-H should also include support for career development.

Ms. West said that ASN is enthusiastic about ARPA-H’s potential to bring new therapies to people living with kidney disease. Kidney disease is costly to the public, has limited treatment options, and disproportionately affects people from minority groups. ARPA-H could complement the growing ecosystem of patient-centered innovation to develop targeted therapies for kidney disease and related conditions, such as diabetes and cancer. ASN welcomes more details about ARPA-H and looks forward to working with the Biden administration, Congress, and the kidney research community to accelerate innovation and improve human health.

Dr. Wysham said that the endocrine system influences the health of all systems in the body and plays a role in the development of several chronic diseases. The Endocrine Society enthusiastically welcomes new use-driven approaches to drive transformational innovation that improves health and also appreciates the early engagement of stakeholders in the establishment of ARPA-H. Fully integrating recent research advances into patient care is going to require funding outside the scope of typical NIH grants. ARPA-H grants will help establish collaborations among scientists from various fields and with industry to help make new technologies and treatments available to all patients. ARPA-H funding should not compete with funding for investigator-initiated research, which will remain essential for the discovery of new opportunities. ARPA-H will also need to ensure that health care solutions are equitably distributed across communities.

Dr. Graham said that people with disabilities face significant health disparities with regard to both access and outcomes. He said that NIH and other federal funding agencies do not often focus on disability research, and it appears that ARPA-H will prioritize disability research. He recommended that ARPA-H continue to consider disability research as a high priority. Also, ARPA-H needs to take advantage of the collective expertise from existing rehabilitation networks both in federal funding agencies and in stakeholder organizations. It will be important for ARPA-H to share data with these federal agencies and stakeholder organizations to advance research in a cost-effective way. It is also critical to obtain ideas and input from several sources to shape ARPA-H’s projects.

Ms. Horan said that the establishment of ARPA-H provides new opportunities for scientific advancement and for ensuring health equity. Traditionally, conditions that mostly or only affect women have not received as much funding as conditions that primarily affect men, and SWHR applauds the implementation of NIH’s Sex as a Biological Variable policy. However, significant gaps remain in understanding conditions that disproportionately or differently affect women. ARPA-H presents an opportunity to adopt, implement, and build on NIH’s policies and to prioritize use-driven research related to women’s health. SWHR recommends that ARPA-H
incorporate a lifespan approach that complements existing NIH research efforts. ARPA-H should prioritize diversity in its leadership and among grant recipients. NIH and OSTP should work directly with organizations at the community, public health, and academic levels to help disseminate information. SWHR recommends offering training for researchers to ensure that they develop projects in an intentional and inclusive way and that their research can be scaled up to maximize impact. Also, ARPA-H should prioritize collaborations with other agencies and stakeholders.

Dr. Cabana said that from the list of ARPA-H priorities, conditions such as asthma and cancer could greatly benefit from expanded pediatric research. Because many of the costly diseases of adulthood have their origins in childhood, there is also a significant opportunity to advance pediatric health by focusing on prevention. However, such initiatives might not yield immediate results, and it is important that ARPA-H consider both the short- and long-term benefits of a project. It is also important for ARPA-H not to prioritize projects based solely on their potential for commercial success.

Dr. Berman said that the Institute for Integrative Health is very enthusiastic about ARPA-H. Although traditional NIH funding mechanisms have led to progress in biomedical research, the upstream drivers of noncommunicable chronic diseases have yet to be studied in detail. The COVID-19 pandemic has shown that the current disease-centric approach to health care is inadequate and has not helped to address health inequities. It is necessary for biomedical research to take an upstream and integrated approach that would promote well-being. The Institute for Integrative Health suggests that to advance personalized medicine and health equity, ARPA-H should prioritize projects that look at the whole individual, including the microbiome and the environmental, psychological, social, and economic factors that influence health. Also, creating a responsive integrative health observatory would provide infrastructure for collaborations and partnerships among different institutions and stakeholders.

Dr. Kligler said that it is important for biomedical researchers to consider a whole health approach instead of focusing on disease-directed outcomes. ARPA-H provides the opportunity to use technology to address the challenge of understanding the complexity of an individual’s well-being and incorporating self-management and self-care into traditional health care. ARPA-H can help establish a learning health care system where individuals have easy access to their health information and can use that information to improve their health. VA is implementing a health care delivery system that could be used to test the feasibility of ARPA-H projects to improve whole health.

Discussion
Dr. Schwetz and Dr. Collins fielded questions submitted through the meeting platform.

- **How can stakeholders submit comments on ARPA-H?** Dr. Collins said that stakeholders can submit comments to the ARPA-H comment box (ARPAHcomments@nih.gov). OSTP and NIH are monitoring these comments and paying close attention to stakeholders’ opinions.

- **Existing research funding mechanisms often concentrate on high-visibility diseases at the expense of others. What is ARPA-H going to do to prioritize underfunded research?** Dr.
Collins said that ARPA-H will fund a wide variety of projects that have opportunities for novel, large-scale, rapid, high-risk, high-reward research, likely including research on rare diseases and diseases without much commercial interest. The ARPA-H director and program managers will be responsible for identifying projects that are most likely to give exciting results in a reasonable period of time, and they will consider stakeholder input when making their decisions.

- **Where will ARPA-H staff be housed?** Dr. Schwetz said that ARPA-H will be housed within NIH because it is important for the agency to have tight connections with NIH’s expertise and infrastructure. However, ARPA-H will be a distinct organization with significant autonomy. The physical location of ARPA-H offices is still under discussion. Although there are several advantages in having these offices located within the Washington, D.C., metropolitan area, there are potential opportunities elsewhere that are worth considering.

- **How soon might solicitations go out?** Dr. Collins said that ARPA-H will adopt a process of rapid solicitations for interest targeted toward finding partners who might not otherwise apply for biomedical research funding from the federal government. Dr. Schwetz agreed and said that an ARPA-H program manager will develop an idea for a project and pitch the idea to the ARPA-H director for rapid review and approval. Once the director approves a project, the project manager will publish solicitations for applications to execute the project. ARPA-H will review applications through a rapid peer review system that will be internally driven by experts across the federal government. ARPA-H will not rank applications but will classify them as either supportable or not supportable. Provided appropriations and authorizations are in place in fiscal year (FY) 2022, it is anticipated that ARPA-H will begin making awards in FY2022. Dr. Collins said that DARPA uses a set of questions, called the “Heilmeier Catechism,” to decide whether a project is suitable for funding.
  - What are you trying to do?
  - How is it done today?
  - What is new in your approach, and why do you think it will be successful?
  - Who cares?
  - What are the risks?
  - What will it cost?
  - How long will it take?
  - What are the midterm and final examinations to measure success?
Dr. Collins said that ARPA-H will follow similar guidelines to determine which projects it will support.

- **How will ARPA-H set its priorities?** Dr. Collins said that ARPA-H will be driven by project opportunities. For ARPA-H to succeed, the most important factor is recruiting the right director and program managers. The director needs to be someone who is not afraid of risks; is an entrepreneur, a visionary, and a good communicator; and understands and appreciates the nuances of biomedical research. The director will recruit 100+ program managers, who will pitch their own project ideas to the director.
• **How will you balance stakeholder interests?** Dr. Collins said that many ARPA-H projects are likely to be platforms that have applications across several disorders. He asked that stakeholders consider how their potential projects will help advance other fields.

• **Will the ARPA-H review process end up causing delays due to multiple cycles of submissions and rejections?** Dr. Collins said that ARPA-H aims to avoid continuous cycles of review not only because they cause delays but also because the program would rather see an exciting high-risk project fail early than fail after multiple cycles of submissions and revisions. He emphasized that ARPA-H will not aim to detract from the work of NIH ICs, because NIH’s efforts have been necessary and successful. Dr. Schwetz said that NIH supports fundamental research that helps build the foundation for ARPA-H. She said that similar parallels exist between DARPA and the National Science Foundation and, on some level, between the Advanced Research Projects Agency-Energy (ARPA-E) and the Department of Energy Office of Science.

• **What will ARPA-H do to address health inequities and disparities in access to health care?** Dr. Collins said that projects to address health inequities will be a critical part of ARPA-H. He said that he, Eric Lander, Ph.D., Dr. Schwetz, and NIH Principal Deputy Director Lawrence A. Tabak, D.D.S., Ph.D., authored an article on ARPA-H that was published in the journal *Science*. The article highlights health equity as a priority and offers examples of projects that could be supported by ARPA-H, including testing a nationwide community health worker model to advance the prevention of illness and management of chronic disease and address health disparities. Dr. Schwetz and Dr. Collins said that suggestions from stakeholders are key to generating new ideas to address health inequities.

• **How will ARPA-H establish collaborations with other fields of research, federal agencies, and industry?** Dr. Schwetz said that interagency collaborations and other partnerships are critical to ARPA-H’s success. OSTP established an interagency working group, co-chaired by OSTP and NIH, that is thinking about how federal agencies can work better together to achieve common goals and promote the mission of ARPA-H. Also, partnerships with industry will be critical to translating new discoveries into commercially available interventions. Collaborations with stakeholders will help develop exciting, transformative ideas.

**Closing**

Francis S. Collins, M.D., Ph.D., Director, NIH

Dr. Collins thanked participants and attendees for their interest in ARPA-H. ARPA-H is a work in progress, and OSTP and NIH will be hosting additional listening sessions to continue gathering information to help guide its establishment. Dr. Collins invited attendees to send comments and questions to the ARPA-H comment box (ARPAHcomments@nih.gov) and to visit the ARPA-H webpage.