

**White House Office of Science and Technology Policy
U.S. Department of Health and Human Services National Institutes of Health
ARPA-H Listening Sessions**

**Listening Session 8: Advocates for Research on Allergies,
Infectious Diseases, and Global Health
August 5, 2021**

The eighth of 10 listening sessions to gather feedback on the proposed Advanced Research Projects Agency for Health (ARPA-H) was held virtually on August 5, 2021, with about 130 attendees. Advocates for research on allergies, infectious diseases, and global health 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

Hugh Auchincloss, M.D., Principal Deputy Director, National Institute of Allergy and Infectious Diseases (NIAID)

Roger I. Glass, M.D., Ph.D., Director, John E. Fogarty International Center

Stakeholders

Suraj Madoori, M.A., M.P.H., M.S.J., U.S. and Global Health Policy Director, Treatment Action Group, New York, NY; Co-Chair, Research Working Group, Federal AIDS Policy Partnership

J. Stephen Morrison, Ph.D., Senior Vice President and Director, Global Health Policy Center, Center for Strategic and International Studies (CSIS), Washington, DC

Jamie Bay Nishi, M.S., Director, Global Health Technologies Coalition, Washington, DC

William Repicci, M.A., President and CEO, Lymphatic Education and Research Network (LERN), New York, NY

Bruce Roberts, Ph.D., Chief Research Strategy and Innovation Officer, Food Allergy Research and Education, McLean, VA

Judith N. Wasserheit, M.D., M.P.H., Founding Board Chair, Research Committee Co-Chair, Consortium of Universities for Global Health, Washington, DC; William H. Foege Chair, Department of Global Health, University of Washington, Seattle, WA

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)

Hugh Auchincloss, M.D., Principal Deputy Director, National Institute of Allergy
and Infectious Diseases (NIAID)

Roger I. Glass, M.D., Ph.D., Director, John E. Fogarty International Center

Dr. Collins welcomed participants and attendees to the eighth 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 a range of 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, and such approaches have 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. Auchincloss noted that NIH has been living in an ARPA-H-like environment for the last 18 months: helping deliver three COVID-19 vaccines in record time and launching joint efforts to develop diagnostics, investigate multisystem inflammatory syndrome in children (MIS-C), and understand Post-Acute Sequelae of SARS-CoV-2 infection (PASC)—or Long COVID. Even so, many people are considering how to do better in the future. An [op-ed in *The Washington Post*](#) by the President's science advisor, OSTP Director Eric S. Lander, Ph.D., proposes a goal of building the capacity to create vaccine within 100 days of detecting a pandemic threat and distributing enough doses to vaccinate people worldwide within 200 days. A disappointing surprise of the pandemic was the small role of monoclonal antibodies, but this experience, too, offers opportunities to improve. To develop good therapeutics, ARPA-H should make use of 21st-century

tools but should follow the successful example of the 20th-century HIV therapeutics program. Artificial intelligence, for example, could be used to derive a protein's structure from its genetic sequence. Food and drug allergies, antimicrobial resistance, and other big challenges are ripe for the bold approach of ARPA-H.

Dr. Glass said there is great potential for global collaboration to address health challenges through ARPA-H. Innovation could offer benefits for noncommunicable diseases and the equitable distribution of care. Global collaboration gives access to the insights and expertise of diverse investigators, accelerating the pace of discovery. The results of such collaboration can be seen in the development of mobile phone-based applications, use of drones that deliver blood and drugs to remote communities, and a reduction in the dose of HPV needed to prevent cancer. Casting a global net to advance worldwide medical practice could bring great rewards. An example is a global dashboard linking populations with unique environmental exposures, including pollution, diet, and the effects of climate change. Big data—such as from wearable devices, point of care diagnostics, or satellite images—could be used to predict and prevent the spread of disease. Studies of populations with rare diseases or unusual presentations of common diseases could offer fresh genetic perspectives, as investigations of groups affected by Huntington's disease in Venezuela and Alzheimer's disease in Colombia have before. There is also promise through global collaboration for low-cost genomic chips for newborn screening or cancer screening. In such collaboration, the principle of equity would be expected, encompassing the sharing of expertise, innovations, and benefits in both directions. In partnership with other ICs, the Fogarty International Center looks forward to contributing its global network of researchers and its expertise in establishing partnerships, building institutions' health research capacity, and developing world leaders in health research.

Comments from Invited Stakeholders

- William Repicci, M.A., President and CEO, Lymphatic Education and Research Network (LERN), New York, NY
- Bruce Roberts, Ph.D., Chief Research Strategy and Innovation Officer, Food Allergy Research and Education, McLean, VA
- J. Stephen Morrison, Ph.D., Senior Vice President and Director, Global Health Policy Center, Center for Strategic and International Studies (CSIS), Washington, DC
- Judith N. Wasserheit, M.D., M.P.H., Founding Board Chair, Research Committee Co-Chair, Consortium of Universities for Global Health, Washington, DC; William H. Foege Chair, Department of Global Health, University of Washington, Seattle, WA
- Jamie Bay Nishi, M.S., Director, Global Health Technologies Coalition, Washington, DC
- Suraj Madoori, M.A., M.P.H., M.S.J., U.S. and Global Health Policy Director, Treatment Action Group, New York, NY; Co-Chair, Research Working Group, Federal AIDS Policy Partnership

Mr. Repicci, speaking on behalf of LERN, underscored the need for lymphatic research and offered the organization as a partner in advancing basic research into the lymphatic system and conditions such as lymphedema and lipedema. Given that women comprise

the majority of patients with these conditions, advancing lymphatic research is a goal that aligns well with the five-year [NIH-wide Strategic Plan](#). Mr. Repicci proposed a Manhattan Project-like effort to find new treatments and cures for lymphatic diseases. He urged NIH to create a national lymphatic commission and establish a center supporting lymphatic research through all NIH ICs that could distribute \$100 million in grant awards annually, including up to \$15 million dedicated to finding a lymphedema cure.

Dr. Roberts spoke on behalf of the food allergy community, urging greater awareness of the food allergy disease burden through its inclusion as an ARPA-H research priority. In particular, ARPA-H could have an impact in the areas of adult-onset allergy, drug discovery, and novel therapies. ARPA-H's innovative approaches should extend to new regulatory approaches for diagnostics. Food-derived proteins, probiotics, immune-modifying antibodies, and vaccines are promising targets for clinical development. With new approaches, successful treatments for allergies to a single food could be used to treat many. He urged ARPA-H to move findings faster to market solutions, while maintaining the integrity of evidence-based science and safety-based review. Finally, as shown by the incorporation of the 2017 [LEAP study](#) findings in guidelines for peanut allergy prevention from NIAID and into federal dietary guidelines, food allergy prevention research has promise and deserves the attention of ARPA-H.

Dr. Morrison offered political and operational advice for setting up the new agency. Primary among lessons learned from standing up similar institutions is that it will take at least three to five years to create the culture of risk-taking, nimble action, and boldness that ARPA-H proposes, and protecting that culture will be a major challenge. Resistance and hostility should be expected, even from within NIH, and critics are likely to imply that the agency's mission and accomplishments are unclear or insufficient. Picking a nontraditional leader with gravitas should be a priority. This person should understand bureaucracy and be adept at managing funding on the scale proposed for ARPA-H, sell the ARPA-H mission widely, manage media, cultivate bipartisan support in Congress, engage champions, and bring in consequential partners. NIH should also be mindful of the political environment and plan accordingly. If control of the House and/or the White House changes, the transfer to Republican power could be disruptive to the new agency. NIH should consider how to protect the leader of ARPA-H. It will be important to stand up some strategic initiatives quickly to demonstrate results and counter critics. ARPA-H is, by definition, different from the NIH ICs, but for both political and operational reasons, it should remain on campus. Nonetheless, it will be important to remind people that ARPA-H is different. ARPA-H should also put equity goals at the forefront, including access to products for low- and middle-income countries (LMICs). Building research and development (R&D) capacity for the next generation and strengthening clinical trials networks globally could help counter antipathy toward the United States resulting from the failures of worldwide COVID-19 vaccine distribution. Dr. Morrison offered CSIS as a willing partner that can bring together experts at the nexus of foreign policy and public health.

Dr. Wasserheit underscored the tremendous enthusiasm and excitement in the CUGH community for ARPA-H's capacity to accelerate breakthrough technologies for health. Four principles must be kept in mind while translating this inspiring vision:

1. ARPA-H must invest in breakthrough technologies for use in LMICs as well as in U.S. tertiary care facilities and labs. It must have a clear mandate to address health needs in LMICs in order to end pandemic disease as we know it and contain emerging diseases.
2. ARPA-H will have the greatest impact by tackling the most pressing complex global challenges—such as antimicrobial resistance, climate change’s impact on health, malnutrition, and diseases of aging—with the most promising scientific opportunities in biomedicine and in information and communication technology, agriculture, environmental and climate sciences, and other nontraditional disciplines.
3. To achieve transformational change, the profound challenges of implementation and scale-up must be addressed through program and policy platforms alongside the development of a robust capacity for implementation science. In addition, ARPA-H must engage early with nations or communities that will use its innovations, in order to understand and incorporate their priorities.
4. Universities—with their expertise, existing partnerships, and commitment to global health research—have a critical role to play as partners. In addition to research grants, ARPA-H could establish a fellowship program analogous to the National Defense Science and Engineering Graduate ([NDSEG](#)) Fellowship Program that would be open to U.S. and LMIC applicants alike and offer sabbatical opportunities to junior faculty.

Ms. Nishi first underscored the importance of investing in ARPA-H with funding and technical expertise that is added to existing investment in R&D. Poverty-related and neglected diseases—such as HIV/AIDS, tuberculosis, malaria and other tropical diseases, and concerns such as antimicrobial resistance—offer an opportunity for transformative breakthroughs and are an area of historic underinvestment compared to their burden. Not only are they afforded relatively little government money, but industry does not invest in this research because of the limited potential for profit. ARPA-H can balance this global inequity and spark innovation in an area of historic market failure. In particular, high-impact gaps that could be transformed by innovation include tools to track the prevalence of neglected tropical diseases, diagnostic platforms, and a highly effective malaria vaccine, perhaps using mRNA technology. Furthermore, investment in infectious disease can benefit health research more broadly, as seen in the contributions of HIV research to understanding COVID-19, malaria drugs used to treat cancer, and use of the BCG tuberculosis vaccine against type 1 diabetes and Alzheimer’s disease. As with its DARPA model, ARPA-H will need policies to give it maximum flexibility in how it distributes funding. Poverty-related and neglected diseases offer opportunities to partner with researchers and end-user communities, building global research capacity and shaping product design. GHTC will look forward to partnering with NIH as the vision for ARPA-H is realized.

Mr. Madoori, representing the 60 organizations that make up the Federal AIDS Policy Partnership Research Working Group, applauded NIH and the administration for their vocal support of ARPA-H. On behalf of the HIV community, he appealed to ARPA-H to prioritize research on HIV and comorbidities, including tuberculosis, STIs, and viral

hepatitis; to partner with the HIV research community; and to promote community-centered research and patient-centered design. The NIAID Community Trials Network has been a successful example of engaging community input in trial protocol and strategy, as well as research priorities. The ARPA-H design should also address structural racism by supporting leadership opportunities for early-stage investigators from disproportionately impacted communities and by increasing recruitment and funding for BIPOC and Latinx researchers, who will bring unique perspectives to research questions and strategies regarding access to and delivery and effectiveness of care. ARPA-H is also positioned to address downstream issues of access and should tackle issues of commercialization, implementation, and affordability of publicly funded research by disclosing the cost of product development and raw materials in agreements with industry and considering the impact of industry incentives. Mr. Madoori expressed high hopes for ARPA-H's ability to lead with a robust structure for community engagement across its portfolio and to prioritize infectious disease.

Discussion

- *What is the nature of a perfect ARPA-H program?* Dr. Collins explained that a successful ARPA-H program will be something that cannot be done within the current system of research support, will be use-driven, can scale, and has outcomes that could change practice and impact biomedical research. The programs will involve partnerships of organizations that do not naturally come together. DARPA evaluates projects using the Heilmeier catechism, based on a set of questions proposed by a former DARPA director:
 - What are you trying to do? Articulate your objectives using absolutely no jargon.
 - How is it done today, and what are the limits of current practice?
 - What is new in your approach and why do you think it will be successful?
 - Who cares? If you are successful, what difference will it make?
 - What are the risks?
 - How much will it cost?
 - How long will it take?
 - What are the mid-term and final “exams” to check for success?

ARPA-H will apply a variation of these questions to health research. The expectation is that projects may fail, but will be pushed to fail early. Unlike many academic research projects, ARPA-H projects will have explicit milestones.

- *How will the ARPA-H program managers and director be recruited, and what qualities will NIH seek to ensure they have a bold mindset?* Dr. Schwetz explained that program manager candidates are likely to be outside-the-box thinkers, people who may have some frustration with the current state and have ideas for innovative solutions to tackle those challenges. NIH will be looking for people from industry, nonprofits, academia, and government, among other places. The 3-to-5-year term for the position will promote a sense of urgency, driving program managers to accomplish everything they want to do. ARPA-H will expand on the urgency engendered in the research response to the pandemic. Also, the ARPA-H director will set the tone for the agency and should be a

- technical expert, an adept leader, an ambassador for the agency, and someone who can help empower staff to embrace the agency's mission.
- *How will ARPA-H collect input on potential ideas?* Dr. Schwetz explained that program managers can be expected to conduct a landscape analysis and market research to vet ideas and ensure they can answer all of the questions posed by the Heilmeier catechism. They will consult experts, meet with stakeholders, and solicit input through workshops, RFIs, and other mechanisms, depending on what is needed for the program.
 - *How will project review happen?* Dr. Collins explained that review is another element of ARPA-H that will differ from the conventional NIH approach. Ideally, a project that is pitched will be approved and launched within months. Dr. Schwetz added that ARPA-H is likely to follow the DARPA model in which the agency gives concepts (abstracts) a quick yes or no, indicating whether there is interest in exploring the idea further. Researchers may then be invited to send in a full application, which would be reviewed by a diverse group of federal employees with expertise in the topic of interest. Proposals will not be given a standard ranking or priority score, but rather a yes or no indicating whether they are suitable for funding. Dr. Collins noted that program managers can reach out to potential partners—for example, a small business developing a relevant technology—and invite them to collaborate and build the appropriate network of expertise.
 - *Will ARPA-H fund research teams with foreign researchers?* Dr. Collins said that ARPA-H-funded research would almost certainly not be limited to only domestic research efforts. It is important to extend NIH's standing as the world's largest supporter of global health research. Dr. Schwetz added that the pandemic emphasized how disease does not know boundaries; likewise, ideas come from diverse sources, and ARPA-H will want to capture the best ideas to solve health problems.
 - *What is the relationship between ARPA-H and other efforts to build pandemic preparedness, such as the development of a prototype vaccine for viral families?* Dr. Auchincloss said that creating prototype vaccines for pandemic preparedness is an ARPA-H-like activity. In fact, this approach was used to develop the COVID-19 mRNA vaccines and is the reason they moved to manufacture so quickly. Dr. Collins added that building ARPA-H and building pandemic preparedness capacity through vaccines that can be targeted to any member of a viral family are ongoing efforts advancing in parallel. It is not yet clear how they will fit together, but they represent great potential for synergy, as outlined in Dr. Lander's op-ed.
 - *What disease areas will be ARPA-H priorities?* Dr. Collins explained that the challenge of proposing a topic for ARPA-H is in framing it in a way that shows it fits the ARPA model. ARPA-H projects are those that are impossible to pursue

through current NIH funding mechanisms. They must be use-driven, with critical needs and potential solutions that ARPA-H could accelerate. Progress toward those solutions must be defined with clear milestones. While the aims might be highly risky, ARPA-H must recognize early when milestones will not be reached and close projects as needed.

- *Is ARPA-H the health version of DARPA?* Yes, that is an apt description, Dr. Collins said. DARPA and ARPA-H do differ. For example, there is basically only a single customer for DARPA outputs, the Department of Defense, but everyone hoping for health advances can be considered customers of ARPA-H. NIH is eager to learn from the lessons of DARPA, both its successes and what did not work well.
- *Are novel prevention devices being considered as a category for ARPA-H funding?* Dr. Collins said emphatically that ARPA-H will include prevention, especially if it touches on health disparities. Health equity is an essential component of ARPA-H, woven into all aspects from the beginning. Prevention strategies in particular should address this issue. Dr. Schwetz added that equity will be considered in all aspects, from program design to hiring staff. While all programs can be expected to tackle equity in a meaningful way, some will target its challenges directly. In addition, identifying a senior leader who ensures that equity issues are considered across programs will be key.
- *How will ARPA-H balance responses to urgent needs with progress toward long-term, complex opportunities?* Dr. Collins noted that this question encapsulates a challenge that will face the ARPA-H director. He emphasized that exciting priorities will include creating platforms that can be applied across disease areas.
- *Does the vision for global research at ARPA-H include having LMIC institutions lead research, not just participate as subcontractors?* Dr. Collins argued that NIH should get away from the colonial model of conducting health research; initiatives like [H3Africa](#) are good examples of how this can be done. Given the immense talent outside of high-income countries, ARPA-H could benefit from pushing the envelope. Dr. Glass added that initiatives that empower LMIC institutions have demonstrated immense creativity and accomplishment. The COVID-19 response, especially given the limitations imposed by travel restrictions, is a key example.

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](#).