DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Advanced Research Projects Agency for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This document announces that the Establishment of the Advanced Research Projects Agency for Health (ARPA-H) is being amended to reflect a revised organizational structure for ARPA-H that aligns with current statutory requirements. *See* 42 U.S.C. 290c(a)(2).

SUPPLEMENTARY INFORMATION: The Establishment of the Advanced Research Projects Agency for Health (ARPA-H) (May 24, 2022, at 87 FR 32174) should now read as follows:

Section I. Mission

The mission of ARPA-H is to (1) expand technical possibilities for the future of health, (2) forge a resilient health ecosystem to ensure optimal well-being for all, (3) drive scalable solutions to improve health care access and affordability, (4) build proactive health capacity to keep people from becoming patients, (5) foster data-driven innovation across the health ecosystem, and (6) increase the probability of successful transition.

Section II. Organization

ARPA-H consists of the following offices and personnel:

The ARPA-H Office of the Director

The ARPA-H Office of the Director (Director's Office (DIRO)) is comprised of:

1. The ARPA-H Director

2. Deputy Director

3. Chief of Staff

4. Such other staff as necessary to support the Office of the Director.

The ARPA-H Director is appointed by the President (42 U.S.C. 290c (1)) and reports directly to the Secretary of Health and Human Services. 42 U.S.C. 290c (3). The Secretary has delegated all determinations regarding ARPA-H programs and operations to be in the sole authority and discretion of the Director. Consistent with 42 U.S.C. 290c(c)(4)(B), this includes all decisions regarding the approval, termination and funding of all ARPA-H projects and programs.

DIRO's functions and responsibilities are as follows: (1) Oversee the creation of agency technical strategy, program approval, prioritization and implementation (2) Lead all aspects of internal Director's Office operations, including ongoing management of the agency's communications, legislative, governmental, legal, international, and mission office activities (3) Serve as the primary liaison for all Executive and Legislative functions of the organization, and fulfills principal level duties across HHS, including engagement with the Secretary and counselors (4) Serve as the primary liaison to Technical Staff, including program managers and their teams, and the Director's Advisory staff to ensure consistent and effective coordination and communication.

The Health Science Futures Office

The Health Science Futures Office (HSFO) is comprised of:

1. Director

2. Deputy Director

3. Such other staff as necessary to support the HSF Director.

The HSFO's functions and responsibilities are as follows: (1) Remove scientific and technological limitations that stymie our nation's progress toward new solutions for the health care of the future. (2) Cultivate novel, agile tools that will facilitate revolutionary advances in medical care. (3) Leverage the latest scientific breakthroughs and invests in the development of

platforms and technologies that do not yet exist. (4) Propose agency-sponsored research programs to the ARPA-H Director, ensuring they align with strategic objectives.

The Resilient Systems Office

The Resilient Systems Office (RSO) is comprised of is comprised of:

1. Director

2. Deputy Director

3. Such other staff as necessary to support the RSO

RSO's mission and responsibilities are as follows: (1) Drive advances in health systems to improve their resilience, robustness, and interoperability, as well as their ability to adapt to unforeseen events, such as cyber-attacks, hospital closures, staffing shortages, emerging pathogens, and natural disasters. (2) Improve the continuity of care during regional and national emergencies, provides time savings to healthcare workforces, enhances quality of care across geographies, improves the robustness of clinical artificial intelligence (AI) applications, makes it easier for patients and clinicians to make informed decisions, and reduces gaps between advanced research and clinical care (3) Develop, implement, and manage novel, innovative scientific and technical programs aimed at improving health outcomes. (4) Propose agency-sponsored research programs to the ARPA-H Director, ensuring they align with strategic objectives.

The Scalable Solutions Office

The Scalable Solutions Office (SSO) is comprised of:

1. Director

2. Deputy Director

3. Such other staff as necessary to support the SSO.

SSO's functions and responsibilities are as follows: (1) Aim to improve health care access and affordability for all Americans by working with partners to streamline manufacturing processes, optimize distribution networks, and develop innovative delivery methods to bring

critical health technologies and treatments to underserved communities and remote areas. (2) Focus on advancing research and development to create scalable health solutions, expanding the reach of proven technologies, and accelerating their integration into the healthcare system. (3) Develop, implement, and manage novel, innovative scientific and technical programs to democratize access to life-saving innovations and reduce disparities in health outcomes across the United States. (4) Propose agency-sponsored research programs to the ARPA-H Director, ensuring they align with strategic objectives.

The Proactive Health Office

The Proactive Health Office (PHO) is comprised of:

1. Director

2. Deputy Director

3. Such other staff as necessary to support the PHO.

PHO's functions and responsibilities are as follows: (1) Improve personal health and wellness to reduce the likelihood that people will become patients. (2) Establish preventative programs that create new capabilities to identify and characterize disease risk, reduce comorbidities, and promote treatments and behaviors to address challenges to Americans' health, whether those are viral, bacterial, physical, psychological, or caused by the natural aging process. (3) Develop, implement, and manage novel, innovative scientific and technical programs aimed at improving health outcomes. (4) Propose agency-sponsored research programs to the ARPA-H Director, ensuring they align with strategic objectives.

The Project Accelerator Transition Innovation Office

The Project Accelerator Transition Innovation Office (PATIO) is comprised of:

1. Director

2. Deputy Director

3. Such other staff as necessary to support the PATIO.

PATIO's missions and responsibilities are as follows: (1) Increase the probability that solutions thrive independently after they transition from ARPA-H. (2) Provide a wide variety of services to Program Managers (PMs) and ARPA-H performers throughout the entire program lifecycle. (3) Provide a tailored, full-suite of entrepreneurial and tech-to-market services to ARPA-H program managers and performers, including access to C-suite level talent to advise on various topics: clinical, business, user adoption, manufacturing, landscape analysis, and regulatory matters. (4) Manage ARPA-H's Small Business Innovation Research (SBIR). (5) Ensure capabilities are primarily designed for user experience. Provide Minimum Viable Product (MVP) and market-testing experimentation to uncover insights into customer desirability, access, and trust. (6) Maintain ARPANET-H, including the Investor Catalyst and Customer Experience Hub and Spoke Network to create a Nationwide Health Innovation Network for ARPA-H to help performers bring their ideas to market. (7) Develop a unique portfolio to address challenging problems related to health for fostering revolutionary advances and paradigm shifts. (8) Propose agency-sponsored research programs to the ARPA-H Director, ensuring they align with strategic objectives.

The Office of Operations

The Office of Operations (OO) is comprised of:

1. Director

2. Deputy Director

3. Such other staff as necessary to support the OO.

OO's functions and responsibilities are as follows: (1) Advise the ARPA-H Director and staff on the planning, development, and implementation of agency Business Operation services. (2) Lead all aspects of internal business operations, including ongoing management of the agency's financial and budget activities, human capital, contracting and acquisitions, and other administrative and operational activities including but not limited to travel and training. (3) Oversee the creation of relevant business operations Standard Operating Procedures (SOPs),

develops tracking and reporting processes and tools, provides high-level input to inform legal and financial risk, and develops systems that support administrative processes within the agency. 4) Oversee the Agency's security related procedures and programs including research security risk and supply chain risk management. (5) Manage ARPA-H's regional footprint and associated infrastructure across hub locations, including facilities and space management. (6) Oversee management of ARPA-H's official records management in collaboration with Office of Information Technology and Data Innovation.

The Office of Information Technology and Data Innovation

The Office of Information Technology and Data Innovation (ITDI) is comprised of:

1. The Chief Technology Officer

2. The Chief Information Officer

3. The Chief Information and Security Officer

4. The Chief Data Officer

5. Such other staff as necessary to support the ITDI Office.

ITDI's functions and responsibilities are as follows: (1) Advise the ARPA-H Director, staff, and programs on every aspect of Information Technology (IT) and Data modernization, governance, and allocation of relevant technology and communication resources to drive the agency's mission. (2) Support the research, development, launch, and maintenance of tools to support data governance, innovation, and analytics across the agency, including data needs for program development. (3) Lead development of agency-wide IT, AI/ML, Technology Infrastructure, Cloud Computing, Networking, End User Computing, Cybersecurity, Technology Compliance, Telecommunications, and Responsible use of Technology Policy. (4) Develop and implement enterprise solutions to enable lean and agile business operations and collaboration. (5) Leads agency efforts to ensure user and data privacy and security management across all platforms and services. (6) Liaise with HHS and across the US government to ensure compliance and consistency with US government policy impacting IT tools and services, as well

as data storage and analysis. (7) Conduct life cycle investment planning and monitoring as needed to support the areas listed above.

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Secretary
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