

AAI Position Statement

Biomedical Research Funding: ARPA-H

Fiscal Year 2026 Recommendation Date Issued: August 22, 2025

Introduction

In March 2022, Congress established the Advanced Research Projects Agency for Health (ARPA-H)¹ as an independent entity within the National Institutes of Health (NIH) to support a portfolio of bold, transformative research that is much riskier than that typically funded through NIH and other federal research agencies, aiming to provide rapid solutions to some of the most difficult and important health care challenges. NIH and ARPA-H are unique and critical components of a vibrant United States (U.S.) scientific enterprise, funding research that spans the entire biomedical research pipeline.

ARPA-H is modeled after the Defense Advanced Research Projects Agency (DARPA), an agency that has played a significant role in the development of many society-changing breakthroughs, including the internet, the global positioning system (GPS), and modern speech translation programs.² While DARPA does have a Biological Technologies Office that funds life sciences research, the office's investments are narrowly intended to "revolutionize our ability to protect the nation's warfighters."³ The creation of ARPA-H has enabled the U.S. to more directly invest in broadly applicable health solutions, such as programs intended to develop better precision cancer therapies, greatly reduce errors made during surgeries, and provide higher-level hospital care for those living in rural America.⁴

Background

ARPA-H was intentionally designed by Congress to operate independently of NIH and other federal funding agencies, with its own leadership, culture, review processes, and funding mechanisms. The agency supports high-risk, high-reward research that has the potential to solve some of America's most significant and insidious health challenges. ARPA-H performers must build specific, measurable milestones into their projects. Program Managers have the authority to quickly terminate any projects that are not meeting their milestones. To date, ARPA-H has demonstrated its ability to launch innovative, groundbreaking initiatives to accelerate the development of solutions for cancer, diabetes, and other major immunology-related diseases that affect millions of Americans.

ARPA-H received a \$1 billion appropriation in fiscal year (FY) 2022 and has since been flat funded at \$1.5 billion for three consecutive years. These funds currently support institutions and investigators across 23 states and three major hubs, dedicated to supporting a nationwide health innovation network called ARPANET-H, located in Dallas, Texas; Boston, Massachusetts; and the National Capital Region. The funds appropriated to

ARPA-H are available for three years, providing flexibility for bold investments and long-term agency planning. While ARPA-H does operate as an independent agency, it is technically housed within NIH. This relationship allows ARPA-H, as needed, to leverage NIH infrastructure, technology, and expertise.

Considerations

Programs Supported by ARPA-H

Each ARPA-H project must seek to answer a big, bold question. Currently funded ARPA-H projects aim to address questions like:

- "what if your immune system could manufacture cures to devastating diseases?" and
- "what if we could bioprint any organ on demand?"

ARPA-H has launched several immunology-focused programs with significant potential for societal impact. The first, EMBODY (Engineering of Immune Cells inside the Body),⁵ aims to revolutionize immune therapies by developing agents that can modify immune cells in the patient, potentially making advanced immunotherapies more accessible and affordable for addressing autoimmune diseases, cancers, and chronic infections. Another program, APECx (Antigens Predicted for Broad Viral Efficacy through Computational Experimentation),⁶ aims to use computer modeling to design vaccines against entire viral families (e.g., flaviviruses, often spread by mosquitoes and ticks), and then develop and test those vaccines in clinical trials, in order to eliminate some of the viral threats responsible for causing cancer, autoimmune diseases, infections, and chronic illness. These and other initiatives supported by ARPA-H exemplify its commitment to high-risk, high-reward research that will transform healthcare. By pioneering innovative approaches to harness or modulate the immune system, these and other similar programs have the potential to create effective, accessible, and affordable treatments for a wide range of diseases, ultimately improving health outcomes for millions of Americans and reshaping the landscape of medical interventions.

Increased funding for ARPA-H is necessary to unlock the possibility of nascent and ongoing ARPA-H programs and to sustain the bold, high-risk innovative research that holds promise to transform and drastically improve the health of Americans. To fully realize this potential without compromising the fundamental discovery supported by NIH, it is essential that ARPA-H funding remains distinct from the NIH budget.

President Trump's Budget Request for ARPA-H

President Trump's budget request for FY 2026 includes a dramatic consolidation of NIH and proposes to move ARPA-H out of NIH entirely into a new entity called Assistant Secretary for a Healthy Future (ASHF), within the Office of the HHS Secretary. ASHF would comprise six major agencies/programs, including the Biomedical Advanced Research and Development Authority, Project Bioshield, and the Strategic National Stockpile. Nearly all of these consolidated programs are focused on pandemic preparedness and response, as well as other health emergencies. ARPA-H has a far broader mission, focused on accelerating disease treatments and transforming healthcare, than these entities and therefore may not be a logical fit within this new entity. Further, any action that might deprive ARPA-H of its independence, including its ability to quickly fund

meritorious proposals and terminate projects that are not meeting pre-established milestones, is concerning and could stand in the way of the agency's goals.

Recommendations

AAI recommends that Congress:

- Provide ARPA-H with at least \$1.7 billion for FY 2026
 This \$200 million increase, which is supported by more than 77 organizations across the biomedical research community,⁸ would provide modest growth for the agency after three consecutive years of flat funding. This growth will enable ARPA-H to invest in a wider range of new programs to accelerate better health outcomes for the American people.
- Maintain ARPA-H as an independent entity
 ARPA-H was established by Congress to act swiftly and independently. Moving it to the newly
 proposed ASHF could threaten its nimbleness and independence.

¹ Congress.gov. 2022. Consolidated Appropriations Act, 2022, Public Law No: 117-103. 117th Congress.

² Bender, Jeremy. 2014. "15 Astounding Technologies DARPA Is Creating Right Now." Business Insider, July 21, 2014.

³ DARPA. n.d. "Biological Technologies Office (BTO)." Defense Advanced Research Projects Agency.

⁴ ARPA-H. n.d. "Programs." Advanced Research Projects Agency for Health.

⁵ ARPA-H. n.d. "EMBODY: Engineering of Immune Cells Inside the Body." Advanced Research Projects Agency for Health.

⁶ ARPA-H. n.d. "APECx: Antigens Predicted for Broad Viral Efficacy through Computational Experimentation." Advanced Research Projects Agency for Health.

⁷ U.S. Department of Health and Human Services. 2025. <u>FY 2026 General Departmental Management Congressional Justification</u>.

⁸ FY 2026 ARPA-H Community Letter