

**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

**Fiscal Year
2024**

Advanced Research Projects Agency for Health

Congressional Justification for Appropriations Committees



DEPARTMENT OF HEALTH & HUMAN SERVICES

Advanced Research Projects Agency for Health



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Director, ARPA-H

I am pleased to present the Advanced Research Projects Agency for Health's (ARPA-H) fiscal year (FY) 2024 Congressional Justification. This budget justification outlines the request for \$2.5 billion to further propel ARPA-H as a fully operational organization executing its' mission - *accelerating better health outcomes for everyone*. With these funds, ARPA-H will continue to launch its inaugural programs, build its mission offices, and recruit program managers (PMs), while finalizing the remaining operational tasks necessary to solidify the agency's presence in the biomedical and health innovation space. Since being sworn in as the Inaugural Director, one of my initial priorities was to help define and protect the unique authorities crucial to mission success of ARPA-H. I appreciate the Congress' support for ARPA-H in the Consolidated Appropriations Act, 2023, which helps lock in the critical authorities and

funding necessary to assure ARPA-H mission success and create an organization that will catalyze breakthrough biomedical innovation.

ARPA-H was established as an independent agency within the National Institutes of Health (NIH) in FY 2023, with the director reporting to the Secretary of Health and Human Services (HHS), granting us the flexibility and independent decision making we need to execute and take big technical risks that can spark new biomedical breakthroughs. Further, the authorities enable us to leverage NIH capabilities to accelerate ARPA-H's immediate business operations, a fundamental component of standing up our new organization. We are grateful for NIH's initial and continued assistance that enables us to quickly acquire talent, manage finances, execute contracts, and obtain equipment while we build our own support team and remain focused in our pursuit of talented PMs for ARPA-H mission launch. NIH collaboration has also been critical for us to align on President Biden's Cancer Moonshot objectives, to ensure unique and impactful contributions from everyone.

Starting a new agency, I recognize the compelling need to communicate and execute a plan to deliver results. To quickly organize and fulfill big agency needs, ARPA-H has implemented industry best practices to align organizational strategic planning, management, and accountability. We have also recruited nearly all our key positions to lead the organization as we move forward on our initial priorities. These priorities bring together business and technical mission areas to meet the milestones necessary for agency culture, technical, and operational success, including building the organization, advancing our programs through recruitment of top PM talent and launching programs, engaging key stakeholders, and advancing strategic management to build trust and accountability in all of our agency processes.

Responding to urgency to address unmet biomedical needs and the aspiration to pursue only the most audacious and impactful programs at ARPA-H's founding, I outlined an approach to effectively communicate critical mission focus areas for investment and orchestrate how ARPA-H will determine the specific programs to fund. To frame this critical answer for our stakeholders, we developed four ARPA-H focus areas: Health Science Futures, Scalable Solutions, Proactive Health, and Resilient Systems.

These focus areas align with key areas where we believe big investment from ARPA-H can significantly advance the state of the art and even change the course of a particular field in a disease agnostic manner.

The four focus areas open a gateway for ideas that present solutions to complex health issues in a manner that is accessible and equitable for all people. The ARPA model necessitates an Agency that is not driven by requirements or top-down strategy, but rather by the ideas and solutions of PMs and their unique vision for efforts that will accelerate the path to better health outcomes for everyone. My immediate goal in FY 2024 is to build our mission offices and recruit up to thirty-five PMs that already have a track record for being action and application oriented in their field. These PMs will have demonstrated expertise in their field (or the boldness to take on a new field) and a passion for solving big problems in health. We are pleased that the initial PM pipeline is generating success; we are moving forward with the recruitment of accomplished PMs ready to execute their ideas starting in late FY 2023.

The entire ARPA-H team is driven by its mission to catalyze health breakthroughs for all Americans. By design, ARPA-H will employ a limited number of full-time federal workforce members (maximum 210 per the Consolidated Appropriations Act, 2023). This core federal team – nearly half of whom will be PMs – will be augmented by a supporting contractor team, which allows for a nimble and flexible workforce to achieve mission success. In support of the PMs and agency leadership, we launched our first solicitation for the development of the contractor workforce that will help to deliver on our day-to-day mission critical activities, providing technical and organizational expertise.

In parallel, we continue to build our network of stakeholders that comprise the complex health ecosystem that ARPA-H serves to augment and enhance. Key stakeholders include the entire HHS enterprise, public and private partners, and our customers – the patients and healthcare providers that will be the ultimate beneficiaries of our investments. Further, we have established a transition element within ARPA-H to ensure seamless “graduation” of programs, tools, and technologies and solutions out of the agency in the safest, most expedient manner possible. For ARPA-H, success will be recognized when innovation sparked within the agency leads to measurably improved health outcomes in the real world, through tools, technologies, and therapeutics that reach our customers – the American people. Perhaps ironically, success at ARPA-H will also include a little bit of failure – creating a culture for innovation and experimentation that ushers in the next moonshots for any number of diseases is another uncompromising component of our organization.

We thrive in a dynamic environment, execute through uncertainty, and learn from failure – adapting and interacting to find solutions. We believe in an equitable and healthier future for all and will forge that reality through rigor, determination, and perseverance.

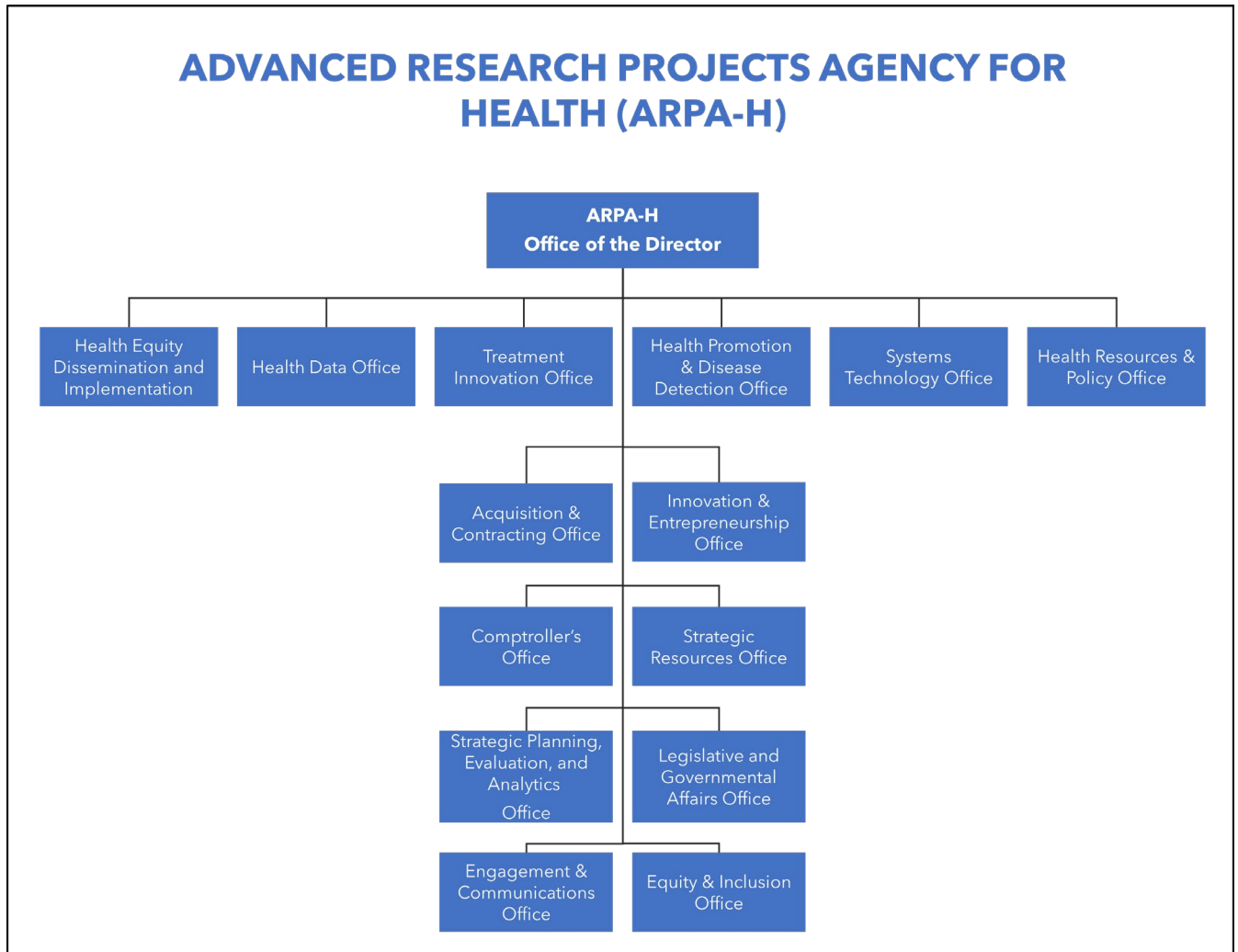
ARPA-H will be a catalyst for all Americans, and there’s an urgency for us to get started.

Renee D. Wegrzyn, PhD

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Organization Chart¹



Note: The ARPA-H structure reported in the Federal Register (Document Number 2022-11519) is consistent with the above organization chart.

<https://www.federalregister.gov/documents/2022/05/27/2022-11519/establishment-of-the-advanced-research-projects-agency-for-health>

¹ In the Consolidated Appropriations Act, FY 2023, ARPA-H is directed to have only up to 8 organization offices. ARPA-H is working to address this direction and would satisfy any congressional notification requirements for future organizations.

Executive Summary

Introduction and Mission

The ARPA-H mission is to accelerate better health outcomes for everyone. ARPA-H is committed to solving the most challenging problems in health by developing research programs dedicated to urgency, excellence, and technical honesty that will accelerate medical breakthroughs that empower every American to realize their full health potential – turning the seemingly impossible to the possible to the actual.

ARPA-H will develop entirely new ways to tackle the hardest challenges in health, by advancing high-potential, high-impact biomedical and health research that cannot be readily accomplished through traditional research or commercial activity. We will execute our mission by creating an environment to support the best ideas from program managers (PMs) who will bring together dynamic teams to solve the toughest health challenges. Our rigorous program design, competitive project selection process, and active program management ensure thoughtful and impactful expenditures. And our streamlined awards process will enable us to act quickly and catalyze cutting-edge biomedical and health research.

ARPA-H mission, execution, and values – to innovate, be responsible, bold, transparent, nimble and diverse – speak to our commitment for health solutions that benefit everyone.

Overview of Budget Request

For FY 2024, the budget request for ARPA-H will continue to support both the establishment of ARPA-H's business operations and launch our mission focus areas of programs. Our FY 2024 budget request is \$2.5 billion, which is \$1.0 billion above the FY 2023 Enacted Level. The request supports the Health and Human Services (HHS) Strategic Goal 4: Restore Trust and Accelerate Advancements in Science and Research for All.

The ARPA-H request accelerates the Agency's launch of high-risk, high reward projects and programs, not readily accomplished through traditional Federal biomedical research and development program or commercial activity. As ARPA-H continues to mature, this request will be the catalyst to launch the inaugural programs, designed to revolutionize the detections, diagnosis, mitigation, prevention treatment, and cure of diseases and health conditions. In FY 2024, ARPA-H will continue to aggressively recruit top talent PMs, leaders in their field, who have identified key problems in health, and are passionate to deliver revolutionary solutions to solve problems in an equitable way.

Strategic Plan

In accordance with the Consolidated Appropriations Act, 2023, ARPA-H is developing a strategic plan to articulate the plans and direction of the Agency, informed by the newly established programs and projects set to begin in FY 2023. Included in this strategic plan will be the ARPA-H path forward to collaborate with federal partners, industry, and academic performers, and to reach stakeholders. These collaborations will be crucial to the achievement of innovative research and sustained, transformative solutions for all individuals.

Focus Areas

Like other Advanced Research Project Agencies (ARPAs), ARPA-H will create new capabilities and solve problems through ambitious, well-defined, and measurable programs each consisting of multiple projects. Each program is led by a PM who champions a core idea, frames the challenge, and awards projects to new multidisciplinary teams of performers, with measurement and evaluation conducted through the process to ensure the best solutions advance. ARPA-H will not have its own labs or facilities.

ARPA-H will make big bets to build high-payoff capabilities or platforms to drive biomedical breakthroughs – ranging from molecular to societal – that will provide transformative solutions for all individuals. The focus areas below illustrate the types of work and impact that ARPA-H may pursue as it hires its first PMs, in FY 2023.

Health Science Futures Focus Area

Expand what is technically possible, creating the tools, technologies, and platforms that can remove limitations that stymie progress towards solutions that can apply to a broad range of diseases.

Scalable Solutions Focus Area

Address health ecosystem challenges that impede equitable, effective, and timely development and distribution of healthcare and disease response at scale. Includes efforts to address innovations that overcome challenges in geography, distribution, manufacturing, data and information, and economies of scale to ensure solutions can reach everyone quickly.

Proactive Health Focus Area

Improve personal health and wellness to reduce the likelihood that people become patients. Proactive health programs will create new capabilities to identify and characterize disease risk, reduce comorbidities, and promote treatments and behaviors to address challenges leading to poor health, whether those are viral, bacterial, physical, psychological, or caused by the natural aging process.

Resilient Systems Focus Area

Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Resilient systems will sustain themselves between crises – from the molecular to the societal – to better achieve outcomes that advance American health and wellbeing to create health resilience at the population level.

Cancer Moonshot

ARPA-H is committed to helping lead and advance the goals of the Cancer Moonshot initiative and investing in the development of transformational technologies. Our objective is to both collaborate with our counterparts across government and empower PMs to use cross-government infrastructure to solve problems and translate technologies for cancer that could only be developed at ARPA-H.

ARPA-H will contribute to Cancer Moonshot by designating a Cancer Moonshot Champion. This champion will identify internal efforts across mission offices that utilize the whole of ARPA-H, engage stakeholders on behalf of the government, and collaborate with Cancer Moonshot leaders in the Office of Science and Technology Policy (OSTP), National Institutes of Health (NIH), the Food and Drug Administration (FDA) and across government.

Further, ARPA-H PMs will also contribute to Cancer Moonshot. PMs can leverage infrastructure (e.g., data, networks) and implementation pathways, translate ongoing research efforts into capabilities for researchers or patients, invest in the development of breakthrough technologies, and solve problems prioritized in the Moonshot that can't be solved otherwise.

ARPA-H will help accelerate the Cancer Moonshot, both through its own research and through collaborations to seize the moment, while maintaining the flexibility for ideas and domains beyond cancer.

Transitioning Capabilities

ARPA-H will drive biomedical and health innovative breakthroughs, by bringing ideas to solutions in the real world. We will accomplish these efforts by,

Design programs that are “ARPA-Hard” and well-defined problems in health

ARPA-H will use the Heilmeier ² framework to answer the questions needed to define these problems, outlining the high risk/high consequences of the stated problem, and identifying those that are appropriately “ARPA-hard” with the potential for high impact that is aligned with the agency mission. ARPA-H will seek stakeholder insights and partner with our federal and community networks to help validate that efforts are not redundant and significantly advance the state of the art.

Build performer teams that bring the most compelling solutions to bear

ARPA-H will use a competitive process to identify optimal industry and academic partners to help solve the greatest challenges to the health ecosystem. We will further leverage the expertise across the Federal government who will provide direct input to our programs as well as amplifying our program opportunities amongst their networks. Through our coordinated efforts, we will minimize duplication and advance new coalitions to advance high-risk/high-reward initiatives.

Execute and measure programs with active program management against metrics

ARPA-H PMs will work closely with program teams, to monitor progress against metrics, budget performance, identify resources and networks to support performer success, and when needed, pivot resources to support the most promising efforts that are likely to result in real world solutions or provide new fundamental insights. PMs will also foster stakeholder engagement throughout to ensure program life cycle, so programs can transition out of the agency and be sustained by funding beyond ARPA-H, whether that is through other funding stakeholders or the commercial marketplace.

Commercialize and transition programs and capabilities for downstream adoption

Success for ARPA-H entails the transition of programs and capabilities out of the agency once the intended capability is demonstrated and the investment is de-risked. Transition of efforts out of ARPA-H may take many forms, ranging from supporting team engagement with stakeholders to securing downstream funding for foundational research projects from other funders in the public or private research enterprise to assisting with company formation or licensing. We will provide mentorship to PMs and to program teams, making connections to customers and investors, and collaborating to de-risk investments.

Conclusion

To achieve transformative research, ARPA-H must thoughtfully and purposely engage its community of customers, stakeholders, and performers.

Our PMs will utilize this community to identify well-defined problems and bring solutions forward that, *survive in the wild* (with solutions real people want and enthusiastically adopt), *separate the improbable*

² Original Heilmeier questions can be found at <https://www.darpa.mil/work-with-us/heilmeier-catechism>

from the impossible (by removing the barriers of today’s technologies and systems), and *deliver better health to everyone* (the healthy, the sick, providers, hospitals, the nation, and the world).

Overview of Performance

In addition to delivering transformative health solutions for everyone, ARPA-H is committed to building an agency culture of continuous improvement and accountability. The agency is prioritizing the development of metrics-driven systems and processes to inform organizational, operational, and programmatic decision-making across all levels. In accordance with the Consolidated Appropriations Act, 2023, ARPA-H is developing a strategic plan that will be completed by December 2023. This plan will help assess and demonstrate how the agency will move forward in achieving its mission over the next five years.

ARPA-H's initial activities focused on hiring the key leadership and support staff required to establish a sustainable and accountable operational structure. Through aligned planning processes, ARPA-H divisions and offices are currently working to set objectives and goals, identify key performance indicators, facilitate evidence-based tracking, and develop transparent reporting structures to evaluate projects and activities.

ARPA-H implemented several essential organizational practices that focus efforts on mission results, while creating agile systems to evaluate and redirect resources to ensure fulfillment of the President’s vision. Agency leadership and program managers (PMs) have defined term limits, creating the urgency and the discipline needed to drive the development and implementation of health solutions at the “speed of relevancy.” In addition, ARPA-H has adopted and enhanced the Heilmeier questions, originally pioneered by the Defense Advanced Research Projects Agency (DARPA), to guide PMs in the development of novel, well-defined problems that cannot be readily addressed through traditional research or commercial activities. ARPA-H has adapted the questions to incorporate the agency-specific tenets of broad population relevance, equity, and real-world applications -- tenets central to the ARPA-H mission.

The Heilmeier questions, requested during the hiring process, also help to ensure that the top PMs with the best ideas are selected by leadership, and that they begin at ARPA-H with a directional focus that increases the likelihood of program success. Together, these organizational parameters help infuse the agency with fresh perspective, while setting a foundation to ensure responsible selection of “high risk, high reward” programs to receive funding.

Once onboard, PMs will be assigned a team including technical, business/financial, and commercialization contractors to support the execution of the program. ARPA-H’s guiding principles stipulate that mission activities and programs will be time-bound and milestone-driven, with clear “mid-term” and “final” exams to evaluate progress and success. PMs will work directly with ARPA-H leadership to develop specific plans with technical milestones that align to program and budget checkpoints. Most program plans will proceed in phases, and program teams are expected to communicate and engage frequently with performers. Monthly, quarterly, and annual reviews will examine progress and budget execution. This high-touch approach will allow PMs to provide guidance and oversight, and to identify failures quickly to redirect resources as needed to assure best use of funds.

Under the leadership of the Director, the operational support staff is also developing goals and best practices to align with the programmatic strategic planning, management, and performance measurement processes. Divisional and staff performance will be measured and tracked relative to the objectives set forth in the strategic plan under development.

To build out agency operations and put ARPA-H on the path toward becoming a transformational health research agency with unique capabilities, the staff is currently refining hiring goals, exploring PM pipeline efficiencies, streamlining and automating onboarding/orientation procedures, and evaluating site locations.

ARPA-H is also committed to building effective financial stewardship and risk management functions that foster prudent use of resources and maintain public trust. The agency is currently standing up operations to deliver accurate, transparent, and on-time financial reports and justifications, develop documentation on standard business processes, and establish integrated data management and governance policies. The agency is pursuing research on integrated solutions that will allow for end-to-end management and tracking of programs.

Finally, the agency is actively pursuing the creation of the network that will support and sustain programs as they exit the ARPA-H portfolio. ARPA-H's transition team and capability has developed campaigns and performed direct outreach to identify potential transition partners and promote awareness of ARPA-H. By the end of FY 2023, the agency expects to engage with hundreds of patient and advocacy groups and create formal contracts with partnership intermediaries through our Partnership Intermediary Agreement (PIA). The PIA will enable rapid engagement through experts with deep transition and commercialization expertise to support PMs even at the inception of their programs to ensure transition upon program completion.

All Purpose Table

All Purpose Table Advanced Research Projects Agency for Health (ARPA-H) <i>(Dollars in millions)</i>								
Activity	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023	
	\$	FTE	\$	FTE	\$	FTE	\$	FTE
ARPA-H								
Total, ARPA-H Program Level	1,000.000	--	1,500.000	135	2,500.000	152	+1,000.000	+17
Total, ARPA-H Discretionary Budget Authority	1,000.000	--	1,500.000	135	2,500.000	152	+1,000.000	+17

Budget Exhibits

ADVANCED RESEARCH PROJECTS AGENCY FOR HEALTH

Appropriation Language

For carrying out section 301 and title IV of the PHS Act with respect to advanced research projects for health, [\$1,500,000,000] \$2,500,000,000, to remain available through September 30, [2025] 2026.[:

Provided, That the President shall appoint in the Department of Health and Human Services a director of advanced research projects for health (Director): *Provided further*, That funds may be used to make or rescind appointments of scientific, medical, and professional personnel without regard to any provision in title 5 governing appointments under the civil service laws: *Provided further*, That funds may be used to fix the compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code:

Provided further, That the Director may use funds made available under this heading to make awards in the form of grants, contracts, cooperative agreements, and cash prizes, and enter into other transactions (as defined in section 319L(a)(3) of the PHS Act): *Provided further*, That activities supported with funds provided under this heading shall not be subject to the requirements of sections 406(a)(3)(A)(ii) or 492 of the PHS Act: *Provided further*, That the Secretary may transfer the Advanced Research Projects Agency for Health, including the functions, personnel, missions, activities, authorities, and funds, within 30 days of enactment of this Act to any agency or office of the Department of Health and Human Services, including the National Institutes of Health: *Provided further*, That the Committees on Appropriations of the House of Representatives and the Senate shall be notified at least 15 days in advance of any transfer pursuant to the preceding proviso].

Language Analysis

ARPA-H was authorized by section 2331 of the Consolidated Appropriations Act, 2023 (PL 117–328). The appropriations language for FY 2024 eliminates language providing authorities that are included in the authorization. The Budget requests funding for ARPA-H as a separate appropriation under NIH rather than as an account under the Office of the Secretary, consistent with the ARPA-H authorization.

Amount Available for Obligation

Advanced Research Projects Agency for Health (ARPA-H) Amounts Available for Obligation <i>(Dollars in millions)</i>			
	FY 2022 Final	FY 2023 Enacted	President's Budget
<u>General Fund Discretionary Appropriation:</u>			
Appropriation (L/HHS, Ag, or Interior)	\$ 1,000.000	\$ 1,500.000	\$ 2,500.000
Across-the-board reductions (L/HHS, Ag, or Interior)			
Subtotal, Appropriation (L/HHS, Ag, or Interior)			
Rescission (other appropriation bills, provide PL #-###)			
Sequestration			
Supplementals			
Reappropriation (provide PL #-###)			
Proposed Supplemental Appropriation			
Proposed Rescission			
Proposed Reappropriation			
Total, Discretionary Appropriation	\$ 1,000.000	\$ 1,500.000	\$ 2,500.000
Unobligated balance, start of year			
Unobligated balance, end of year	\$ 956.000		
Unobligated balance, lapsing			
Total obligations	\$ 44.000	\$ 1,500.000	\$ 2,500.000

Summary of Changes

Advanced Research Projects Agency for Health (ARPA-H)						
Summary of Changes						
(Dollars in millions)						
FY 2023 Enacted						
Total estimated budget authority.....					\$1,500.000	
(Obligations).....						
FY 2024 President's Budget						
Total estimated budget authority.....					\$2,500.000	
(Obligations).....						
Net Change.....					+\$1,000.000	
	FY 2023 Enacted		FY 2024 President's Budget		FY 2024 +/- FY 2023	
	BA	FTE	BA	FTE	BA	FTE
Increases:						
Built-in:						
Annualization of 2023 commissioned corps pay increase.....	\$ 37.611	135	\$ 46.783	152	\$ 9.172	17
Annualization of 2023 civilian pay increase.....	\$ 37.611	135	\$ 46.783	152	\$ 9.172	17
Subtotal, Built-in Increases.....	\$ 37.611	135	\$ 46.783	152	\$ 9.172	17
B. Program:						
1. Establishment of ARPA-H Offices and Program Focus Areas .	\$ 1,462.389		\$ 2,453.217		\$ 990.828	0
Subtotal, Program Increases.....	\$ 1,462.389		\$ 2,453.217		\$ 990.828	0
Total Increases.....	\$ 1,500.000	135	\$ 2,500.000	152	\$ 1,000.000	17
Decreases:						
A. Built-in:						
1. Pay Costs.....	\$ -		\$ -		\$ -	0
Subtotal, Built-in Decreases.....	\$ -		\$ -		\$ -	0
B. Program:						
1. Name of Reduced Program	\$ -		\$ -		\$ -	0
2. Eliminated Program: Program Name.....	\$ -		\$ -		\$ -	0
Subtotal, Program Decreases.....	\$ -		\$ -		\$ -	0
Total Decreases.....	\$ -		\$ -		\$ -	0
Net Change.....	\$ -		\$ -		\$ 1,000.000	17

Budget Authority by Activity

Advanced Research Projects Agency for Health Budget Authority by Activity <i>(Dollars in millions)</i>			
	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Total, ARPA-H Program Level	\$ 1,000.000	\$ 1,500.000	\$ 2,500.000
Total, Budget Authority FTE	\$ 1,000.000 0	\$ 1,500.000 135	\$ 2,500.000 152

Authorizing Legislation

<p>Advanced Research Projects Agency for Health (ARPA-H)</p> <p>Authorizing Legislation</p> <p>(Dollars in millions)</p>				
	FY 2023 Amount Authorized	FY 2023 Amount Appropriated	FY 2024 Amount Authorized	FY 2024 President's Budget
<p><u>Activity:</u></p> <p>ARPA-H programs</p> <p>Part J, Title IV of the Public Health Service Act, Section 499 A</p>	\$ 1,500.000	\$ 1,500.000	\$ 500.000	\$ 2,500.000

Appropriation History Table

Advanced Research Projects Agency for Health (ARPA-H) Appropriations History Table (Dollars in millions)				
	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
FY 2022	\$ -	\$ -	\$ -	\$ 1,000.000
FY 2023	\$ 5,000.000	\$ 2,750.000	\$ 1,000.000	\$ 1,500.000
FY 2024	\$ 2,500.000			

Summary of the Request

ARPA-H's FY 2024 President's Budget request will continue to support ARPA-H's mission. The FY 2024 budget request for ARPA-H is \$2.5 billion, which is +\$1.0 billion or 67% increase above the FY 2023 Enacted Level. At this level, ARPA-H will continue to aggressively stand-up the agency with the focus to hire 210 FTEs (by steady state) and establish a portfolio of programs under each mission office.

In FY 2024, ARPA-H estimates staffing at 152 FTEs comprised of program managers and operational staff. The requested funding will support the continued establishment of ARPA-H mission offices, the recruitment of program managers, and the creation of high-impact programs for viable health solutions. Mission office focus areas include health science futures, scalable solutions, proactive health and resilient systems.

ARPA-H is currently authorized through the Consolidated Appropriations Act, 2023 (PL 117-328). The law amends Title IV of the Public Health Service Act by establishing ARPA-H within NIH, allowing the Secretary to transfer all functions, personnel, missions, activities, authorities, and funds from the Office of the Secretary.

Authorizing Language: ARPA-H is authorized through the Consolidated Appropriations Act, 2023.

Allocation Method: ARPA-H has authority to allocate funding via direct federal/intramural, contract, grant, cooperative agreement; cash prize; and other transaction.

Narrative by Activity

Header information

Advanced Research Projects Agency for Health (ARPA-H)

(Dollars in millions)

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
BA	\$ 1,000.000	\$ 1,500.000	\$ 2,500.000	\$ 1,000.000
Program Level	\$ 1,000.000	\$ 1,500.000	\$ 2,500.000	\$ 1,000.000
FTE		135	152	17

Program Description

On March 15, 2022, the ARPA-H was formally established as an independent entity within the NIH, directly reporting to the Secretary of HHS. Operationally distinct from NIH's Institutes and Centers, the ARPA-H continues to make extraordinary progress in distinguishing itself as a uniquely positioned Agency in the pursuit of high risk, high reward biomedical achievements *that accelerate better health outcomes for everyone*.

The ARPA-H will drive transformational innovation by fostering the development of novel, breakthrough, and broadly applicable capabilities and technologies, addressing health problems that cannot be readily accomplished through traditional research or commercial activity. The ARPA-H programs will break historical barriers, promote high-risk, high reward innovations, and achieve equitable outcomes.

Budget Request

The FY 2024 Budget Request for ARPA-H is \$2.5 billion, which is +\$1.0 billion above the FY2023 Enacted Level. At this funding level, ARPA-H plans to recruit 35 Program Managers who will oversee approximately 70–100 programs and will continue to establish the agency, scientific programs, and business operations, with the goal of achieving the President’s vision.

Five Year Funding Table

FY 2020	\$ -
FY 2021	\$ -
FY 2022 Final	\$ 1,000,000
FY 2023 Enacted	\$ 1,500,000
FY 2024 President's Budget	\$ 2,500,000

Program Accomplishment

The agency has begun to tackle these ambitious challenges, making extraordinary progress towards a highly functional Agency that is well on its way to operational success. This includes an accelerated approach to propelling ARPA-H into the health ecosystem landscape - establishing mission direction, creating organization structure, and launching program development – while also creating community with potential federal, industry, non-profit and academia performers and partners.

ARPA-H has organized its agency development around an established set of key activities and goals that continue to drive organizational accomplishments.

First, by building a world class team with a *focus on strategic priorities* toward four key mission focus areas: Health Science Futures, Scalable Solutions, Proactive Health and Resilient Systems.

Second, by building a *nimble operational culture and structure*, one that leverages program management teams, cultivates a modernized workspace, and values taking great risks to generate high reward while also learning from failures.

Third, framing for execution, the ARPA-H’s distinct role within the health ecosystem, bridging large-scale, sustained, and cross-sector coordination of biomedical partnerships, while educating and exciting stakeholders and the broader public.

Building a World Class Team with a Focus on Strategic Priorities

Operational Staff and Leadership

To meet the Agency's strategic priorities and foundational goals, the ARPA-H Director is actively building an organization of talented operational staff to drive the execution of the ARPA-H mission. As of January 2023, the Agency

- Hired a team of over 100 government, contract, fellows and detailees.
- Selected members of the ARPA-H leadership team towards onboarding and filling almost 50% of key positions with highly recognized experts.

An attribute to the agility of the DARPA organizational model, is the use of a large proportion of specialized contractor support (known as SETAs, Science and Engineering Technical Advisors) throughout the Agency. Adopting this approach, the ARPA-H contractor support is expected to grow to a steady-state proportion of approximately 5 contractors per federal employee. This agency-level key performance indicator will assist the agency in remaining nimble and responsive to program portfolio performance.

Program Manager Pipeline

In parallel to the operational staff and leadership recruitment, the ARPA-H is actively onboarding visionary PMs. The ARPA-H approach to recruitment of PMs is carefully designed to attract and promote a diverse and inclusive collective of individuals with program ideas impacting broad populations across the biomedical and health landscape. The ARPA-H applicant pool reflects this fundamental requirement, with scientific and technical experts from industry, academia, and think tanks, all with an array of bold program ideas anticipating high-risk, high-reward research impact.

- ARPA-H developed and implemented a PM outreach and recruitment strategy to build a pipeline that reflects the expertise and diversity necessary to achieve the ARPA-H mission.

Like DARPA, ARPA-H PMs will be term-limited for 3-6 years, infusing the Agency with unique, fresh perspective and lean-forward urgency towards measurable results. A robust and ongoing pipeline of talented leaders will be an essential element of agency success. Efforts to support top of funnel national recruitment, will require significant multi-year investments and ongoing operational resources to build the brand and the critical networks to attract top talent to feed this crucial pipeline.

Strategic Priorities

Chosen ARPA-H PMs are top-of-field and bring broad-impact, well-defined health problems or opportunities, which are further vetted and refined by agency leadership during the hiring process. For project consideration, ARPA-H program managers must present concepts that encompass one or more of the agency's four research focus areas – health science futures, scalable solutions, proactive health and resilient systems. PMs launch their initial concept of ideas by answering the ARPA-H Heilmeier questions.

Heilmeier Approach

Like DARPA, the agency will be using a version of the Heilmeier Questions as a framework to assess the challenge, approach, relevance, risk, duration, and metrics of success. However, to ensure the ARPA-H standard for diversity and equity in biomedical and health research, the original questions have been modified to reflect ARPA-H's scope and values, by

- Prioritizing reaching people where they are and focusing on equitable health solutions

- Augmenting the rubric to include evaluation of accessibility and user experience to ensure research innovations and solutions have widespread adoption potential
- By directly focusing some programs and projects on addressing health disparities and health equity; all programs and projects will consider equity in their design and implementation

All ARPA-H programs are evaluated using the questions below:

1. What are you trying to do? What health problem are you trying to solve?
2. How does this get done at present? Who does it? What are the limitations of present approaches?
3. What is new about our approach? Why do we think we can be successful at this time?
4. Who cares? If we succeed, what difference will it make?
5. What are the risks? That may prevent you from reaching your objectives? Any risks the program itself may present?
6. How long will it take?
7. How much will it cost?
8. What are our mid-term and final exams to check for success?

The ARPA-H additional Heilmeier equity questions:

1. To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?
2. How might this program be misperceived or misused (and how can we prevent that from happening)?

ARPA-H has expanded the criteria for proving a program design is worthy of funding by augmenting the Heilmeier questions to include the adoption of accessibility and user experience, critical to ensuring health equities across all research programs.

Execution of Programs

ARPA-H will seek program managers and performers from across the country with the ability to execute programs from locations throughout the nation. Program managers will effectively be recruited and sought to manage and execute these programs from various sites, working closely with performers and stakeholders, to ensure achievement of project success.

ARPA-H will effectuate programs and projects through its authority to award grants, cooperative agreements, procurement contracts, cash prizes, and other transactions. The primary vehicle to execute these programs and projects quickly will be the use of Broad Agency Announcements (BAA) issued on an office-wide and a program-specific basis. The ARPA-H anticipates the first office-wide BAA will post third quarter FY 2023 and will remain open for up to five years.

We expect project awards (within their accepted programs) to support performers in industry, universities, non-profit research institutions and federal agencies. This cultivates the top talent necessary to produce transformative research to drive biomedical and health breakthroughs.

Building a Nimble Operational Culture and Structure

Operational Culture

ARPA-H's success will rely on the promotion of a culture that is administratively and scientifically nimble. ARPA-H values a relentless drive for transformative technical results and a willingness to take high technical and programmatic risks. The structure of ARPA-H is meant to be flat and flexible, to enable an unfettered environment that is necessary to achieve the Agency mission. The staff need to be

free to innovate at the “speed of relevance” and ARPA-H is dedicated to minimizing hierarchy to help achieve this imperative need.

ARPA-H seeks to realize solutions to hard problems by empowering individual program managers to pursue high-risk, high-reward research and development. The Agency will,

- Drive organizational design around a service model for program managers – from financial account structure to SETA support to customized analyses
- Develop spend plans to support the need to remain agile in project award execution while also continuing to build and sustain the support functions for agency business operations
- Leverage NIH business systems and processes where applicable for development of program account structures and to promote immediate means for accountable and transparent funding and program execution, and develop ARPA-H systems and processes where NIH’s capability is not sufficient

Each ARPA-H PM may champion an average of 3-5 programs during their tenure, launching on average one program per year. All PMs will commence programmatic activities immediately upon hire. The PMs, to ensure focused and efficient execution, will set technical strategies, leverage the expertise of team members, and provide active oversight of performers and participants relative to specific program metrics.

Given the nature of the high stakes programs that will define ARPA-H, failure is expected—otherwise the agency itself is failing to embrace risk by investing in projects that cannot readily be accomplished through traditional research or commercial activity. Similar to DARPA, ARPA-H anticipates a substantial project failure rate. Failure will mean that the program did not meet its full stated objectives; however, it is expected that as programs progress, discovery will occur and may provide new avenues for exploration and program development.

New information systems and technologies, like Application Programming Interfaces, will be developed, acquired, and implemented to extend the capabilities of existing technology systems as the Agency grows. This informational backbone will ensure that resources, to include funding and support expertise, can be quickly and efficiently shifted toward new opportunities or more promising projects of impact, ensuring best use of taxpayer funds.

Operational Structure

In addition to the creation of a program manager-centered model, ARPA-H swiftly set critical Agency business processes that promote the efficient and effective infrastructure to enable Agency operations. The ARPA-H,

- Awarded a short-term contract for flexible workspace, enabling in-person engagement in multiple locations that meets current ARPA-H agility needs and supports the agency’s efforts to maintain a small physical footprint at minimal cost
- Received acquisition authority up to \$100 million from Health and Human Services, Assistant Secretary for Financial Resources (HHS/ASFR), with warrants to ARPA-H acquisition staff, promoting further agency operational flexibility and independence
- Initiated a novel approach to supporting program transition through a Partnership Intermediary Agreement (PIA) between the government and intermediary organizations to assist with technology transfer and transition.

ARPA-H recognizes the importance of its physical location to operational success. With the goal to fund and execute the most promising ideas to help create high-impact solutions, ARPA-H will determine location based on a defined set of criteria and in accordance with the Consolidated Appropriations Act, 2023. To move this effort forward, ARPA-H,

- Notified Congressional Committees in January 2023 of the start of the site selection search
- Established criteria, set goals and anticipates providing additional site selection details to Congressional Committees in March 2023

The ARPA-H site selection decision is crucial to the Agency’s ability to easily collaborate with performers while also reaching stakeholders. The ARPA-H seeks scalable space to accommodate growth, proximity to regulatory and other governmental partners, as well as access to the broader biomedical and health ecosystem.

Frame ARPA-H’s Positioning and Engage Critical Stakeholders

ARPA-H Positioning

Recognizing the importance of creating ARPA-H’s unique positioning within the health ecosystem, the Agency has actively sought to connect and communicate with the public, the media, and partners and stakeholders within government and industry.

ARPA-H continues to promote the accessibility and consistency of the ARPA-H message through a cohesive communications plan, including (as of February 2023),

- Launch of the [ARPA-H website](#) on November 14, 2022. Since launch the site has been visited by 24,718 unique users who have viewed the site 98,134 times. Besides the homepage, the most popular pages are the PM application page and the “Work With Us” employment opportunities page.
- Social media drive (Twitter, LinkedIn, YouTube, Instagram), with 4,200 total followers (and growing!) and average engagement rate of 7.16%

In addition, ARPA-H is implementing a media and public relations strategy to educate the public regarding the ARPA-H mission.

- ARPA-H conducted a multi-media interview blitz day that resulted in several high-visibility articles, including Bloomberg, Science, STAT News, with interviews also conducted with New York Times, AP, WIRED, among others

Engaging Critical Stakeholders

Within the Department of Health and Human Services, ARPA-H has also sought to develop strong, collaborative relationships with the NIH Institutes and Centers and other key agencies such as the Centers on Disease Control and Prevention, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Administration for Strategic Preparedness and Response, the Office of Minority Health, the Administration for Community Living, the Agency for Healthcare Research and Quality, and the Health Resources and Service Administration.

These collaborations are important for transition of ARPA-H program outcomes, as well as in identifying critical needs and opportunities and creating partnerships on complex projects that interact with public health infrastructure or medical regulation.

- For example, ARPA-H will appoint a Cancer Moonshot Champion, to identify internal efforts aligned to Cancer Moonshot and empower ARPA-H Program Managers to use cross-government infrastructure to seize the moment to solve problems and translate technologies to address cancer that could only be developed at ARPA-H.

It has also been important for ARPA-H to engage with the broader biomedical and health communities, including patients and their caregivers, researchers, industry, community groups, and others, to understand the full range of problems and the practical considerations that need to be addressed for all groups and populations. ARPA-H has,

- Participated in engagements with more than 100 patient advocacy groups, government, and professional associations.
- Established the goal to create a community of hundreds of patient groups, to build relationships for ideas and promote accountability within its research groups

To speed progress on every front, ARPA-H will leverage novel public-private partnerships; use directive approaches providing quick funding decisions to support projects that are results-driven and time-limited; and identify emergent opportunities through advanced systematic horizon scans of academic and industry efforts. ARPA-H has,

- Met with 20 universities' administrators, vice chancellor/vice presidents of research, and associated faculty virtually and in-person across the country.
- Discussed concept pitches and met potential PMs aligned to mission thrust areas, venture capitalists, investors, and potential future performers in-person in major U.S. Cities
- Conducted engagements with potential research transition partners in Atlanta, Boston, New York and San Francisco

As ARPA-H continues to establish itself in the biomedical and health sphere, it will develop, promote and solidify clear and key programs to accelerate transformative innovation biomedical science and medicine. These high-risk, high-reward programs will remain undeterred in the advancement of diverse and equitable health solutions, contributing to the United States goal to maintain leadership in science and innovation while also improving the health and wellbeing of its citizens.

Outputs and Outcomes Table

The ARPA-H will determine performance metrics after establishing initial programs, tentatively planned for late summer FY2023.

Supplementary Tables

Budget Authority by Object Class

Advanced Research Projects Agency for Health (ARPA-H)				
Budget Authority by Object				
<i>(Dollars in thousands)</i>				
	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
<u>Personnel compensation:</u>				
Full-time permanent (11.1)		\$ 27,963	\$ 34,783	\$ 6,819
Other than full-time permanent (11.3)		\$ 280	\$ 348	\$ 68
Other personnel compensation (11.5)				\$ -
Military personnel (11.7)				\$ -
Special personnel services payments (11.8)				\$ -
Subtotal personnel compensation	\$ -	\$ 28,243	\$ 35,131	\$ 6,887
Civilian benefits (12.1)		\$ 9,368	\$ 11,652	\$ 2,284
Military benefits (12.2)				\$ -
Benefits to former personnel (13.0)				\$ -
Total Pay Costs	\$ -	\$ 37,611	\$ 46,783	\$ 9,172
				\$ -
Travel and transportation of persons (21.0)	\$ 1	\$ 10,340	\$ 10,588	\$ 248
Transportation of things (22.0)		\$ 10	\$ 10	\$ 0
Rental payments to GSA (23.1)				\$ -
Rental payments to Others (23.2)		\$ 7,800	\$ 7,987	\$ 187
Communication, utilities, and misc. charges (23.3)		\$ 254,484	\$ 260,592	\$ 6,108
Printing and reproduction (24.0)		\$ 5	\$ 5	\$ 0
				\$ -
<u>Other Contractual Services:</u>				\$ -
Advisory and assistance services (25.1)	\$ 10,663	\$ 13,000	\$ 20,000	\$ 7,000
Other services (25.2)	\$ 4,318	\$ 392,515	\$ 401,935	\$ 9,420
Purchase of goods and services from government accounts (25.3)	\$ 28,910	\$ 60,250	\$ 61,696	\$ 1,446
Operation and maintenance of facilities (25.4)			\$ -	\$ -
Research and Development Contracts (25.5)		\$ 723,585	\$ 1,689,994	\$ 966,409
Medical care (25.6)				\$ -
Operation and maintenance of equipment (25.7)				\$ -
Subsistence and support of persons (25.8)				\$ -
Subtotal Other Contractual Services	\$ 43,892	\$ 1,461,989	\$ 2,452,808	\$ 990,818
				\$ -
Supplies and materials (26.0)		\$ 300	\$ 307	\$ 7
Equipment (31.0)	\$ 89	\$ 100	\$ 102	\$ 2
Land and Structures (32.0)				\$ -
Investments and Loans (33.0)				\$ -
Grants, subsidies, and contributions (41.0)				\$ -
Interest and dividends (43.0)				\$ -
Refunds (44.0)				\$ -
Total Non-Pay Costs	\$ 89	\$ 400	\$ 410	\$ 10
Total Budget Authority by Object Class	\$ 43,981	\$ 1,500,000	\$ 2,500,000	\$ 1,000,000

Salaries and Expenses

Advanced Research Projects Agency for Health (ARPA-H)				
Salaries and Expenses				
(Dollars in thousands)				
	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Personnel compensation:				
Full-time permanent (11.1).....	\$ -	\$ 27,963	\$ 34,783	\$ 6,819
Other than full-time permanent (11.3).....	\$ -	\$ 280	\$ 348	\$ 68
Other personnel compensation (11.5).....	\$ -	\$ -	\$ -	\$ -
Military personnel (11.7).....	\$ -	\$ -	\$ -	\$ -
Special personnel services payments (11.8).....	\$ -	\$ -	\$ -	\$ -
Subtotal personnel compensation.....	\$ -	\$ 28,243	\$ 35,131	\$ 6,887
Civilian benefits (12.1).....	\$ -	\$ 9,368	\$ 11,652	\$ 2,284
Military benefits (12.2).....	\$ -	\$ -	\$ -	\$ -
Benefits to former personnel (13.0).....	\$ -	\$ -	\$ -	\$ -
Total Pay Costs	\$ -	\$ 37,611	\$ 46,783	\$ 9,172
			\$ -	\$ -
Travel and transportation of persons (21.0).....	\$ 1	\$ 10,340	\$ 10,588	\$ 248
Transportation of things (22.0).....	\$ -	\$ 10	\$ 10	\$ 0
Rental payments to GSA (23.1).....	\$ -	\$ -	\$ -	\$ -
Rental payments to Others (23.2).....	\$ -	\$ 7,800	\$ 7,987	\$ 187
Communication, utilities, and misc. charges (23.3).....	\$ -	\$ 254,484	\$ 260,592	\$ 6,108
Printing and reproduction (24.0).....	\$ -	\$ 5	\$ 5	\$ 0
		\$ -	\$ -	\$ -
Other Contractual Services:		\$ -	\$ -	\$ -
Advisory and assistance services (25.1).....	\$ 10,663	\$ 13,000	\$ 20,000	\$ 7,000
Other services (25.2).....	\$ 4,318	\$ 392,515	\$ 401,935	\$ 9,420
Purchase of goods and services from government accounts (25.3)	\$ -	\$ -	\$ -	\$ -
Operation and maintenance of facilities (25.4).....	\$ 28,910	\$ 60,250	\$ 61,696	\$ 1,446
Subtotal Other Contractual Services.....	\$ 43,892	\$ 738,404	\$ 762,813	\$ 24,410
Supplies and materials (26.0).....	\$ -	\$ 300	\$ 307	\$ 7
Equipment (31.0).....	\$ 89	\$ 100	\$ 102	\$ 2
Total Non-Pay Costs	\$ 43,981	\$ 738,804	\$ 763,223	\$ 24,419
				\$ -
Total Salary and Expense	\$ 43,981	\$ 776,415	\$ 810,006	\$ 33,591
Direct FTE		135	152	17

Detail of Full-Time Equivalent Employment (FTE)

The Advanced Research Projects Agency for Health Detail of Full Time Equivalents (FTE)									
	2022 Actual Civilian	2022 Actual Military	2022 Actual Total	2023 Est. Civilian	2023 Est. Military	2023 Est. Total	2024 Est. Civilian	2024 Est. Military	2024 Est. Total
Director's Office									
Direct:	0	0	0	4	0	4	4	0	4
Reimbursable:			0	0	0	0	0	0	0
Total:	0	0	0	4	0	4	4	0	4
Chief Information Officer									
Direct:	0	0	0	8	0	8	8	0	8
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	8	0	8	8	0	8
Data Analytics									
Direct:	0	0	0	3	0	3	3	0	3
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	3	0	3	3	0	3
Acquisition & Contracting Office									
Direct:	0	0	0	21	0	21	21	0	21
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	21	0	21	21	0	21
Strategic Resource Office									
Direct:	0	0	0	12	0	12	12	0	12
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	12	0	12	12	0	12
Comptroller Office									
Direct:	0	0	0	15	0	15	15	0	15
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	15	0	15	15	0	15
Project Accelerator Transition Innovation Office									
Direct:	0	0	0	7	0	7	7	0	7
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	7	0	7	7	0	7
Engagement & Communications Office									
Direct:	0	0	0	13	0	13	13	0	13
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	13	0	13	13	0	13
Office of General Counsel									
Direct:	0	0	0	7	0	7	7	0	7
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	7	0	7	7	0	7
Legislative & Governmental Affairs Office									
Direct:	0	0	0	4	0	4	4	0	4

The Advanced Research Projects Agency for Health Detail of Full Time Equivalents (FTE)									
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	4	0	4	4	0	4
Director's Office-Special Projects									
Direct:	0	0	0	4	0	4	4	0	4
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	4	0	4	4	0	4
Mission Support Service									
Direct:	0	0	0	6	0	6	6	0	6
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	6	0	6	6	0	6
Mission Office									
Direct:	0	0	0	8	0	8	12	0	12
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	8	0	8	12	0	12
Mission Office									
Direct:	0	0	0	8	0	8	12	0	12
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	8	0	8	12	0	12
Mission Office									
Direct:	0	0	0	7	0	7	12	0	12
Reimbursable:	0	0	0	0	0	0	0	0	0
Total:	0	0	0	7	0	7	12	0	12
OPDIV FTE Total	0	0	0	135	0	135	152	0	152
Average GS Grade									
FY 2020	N/A								
FY 2021	N/A								
FY 2022	N/A								
FY 2023	15.4								
FY 2024	15.6								

Detail of Positions

Advanced Research Projects Agency for Health (ARPA-H)			
Detail of Positions			
	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Executive level I			
Executive level II		2	2
Executive level III		1	1
Executive level IV		2	2
Executive level V			
Subtotal Executive Level Positions		5	5
Total - Exec. Level Salaries		\$1,060,500	\$1,115,646
Subtotal ES positions			
Total - ES Salary			
GS-15		43	43
GS-14		44	44
GS-13		10	10
Subtotal		97	97
Total - GS Salary		\$16,917,970	\$17,797,704
Ungraded			
Administratively Determined		32	49
T42		1	1
Subtotal		33	50
Total - Ungraded salaries		\$9,985,000	\$15,869,420
Average ES level		2	2
Average ES salary		\$212,100	\$223,129
Average GS grade		15.4	15.6
Average GS salary		\$174,412	\$183,481
Average Special Pay categories			
Administratively Determined		\$300,000	\$312,000
T42		\$385,000	\$405,020