



Comments for NIH and OSTP listening session on the proposed ARPA-H on August 4, 2021:

Thank you for this opportunity. I'm Ellie Dehoney, Research!America's Vice President for Policy and Advocacy.

Research!America is a national nonprofit, nonpartisan alliance spanning patient advocates and the health-focused R&D ecosystem of which patients are part.

We know that medical and public health progress is urgently needed, but hard-won.

We are tremendously grateful to the President for refusing to settle for the status quo.

Patients – and in the arc of our lives, we are all patients – cannot afford stasis.

We fully support the Administration and members of Congress from both sides of the aisle in their efforts to stand-up ARPA-H.

We envision ARPA-H as a resolutely independent incubator, capitalizing on best practices from DARPA and ARPA-E and forging new ground at the intersection of public, private, academic and philanthropic efforts to advance health.

Regarding where ARPA-H is situated within the federal government, at this point our alliance members hold divergent views, so Research!America has not taken a position.

However, based on two alliance member listening sessions and continuing input, there is considerable consensus around the following recommendations:

First, it is crucial for safeguards to be put into place that prevent ARPA-H funding from supplanting NIH investment.

In the same vein and by design, ARPA-H investment should not supplant private sector investment.

ARPA-H should build out – not crowd out – progress.

In that context, we strongly oppose funding Taps that divert dollars from NIH into ARPA-H. We also believe NIH should be waived from any co-funding with ARPA-H.

While ARPA-H should have the flexibility to fully fund NIH-associated projects, co-funding would counter-productively draw down from NIH grant and intramural investment.

Further, regardless of whether ARPA-H reports to the NIH Director, it is worth considering establishing ARPA-H as a stand-alone entity physically, structurally, and statutorily distinct from any existing federal agency or program.

The independent entity approach could entail creating a dual role for the NIH director, with separate and distinct responsibilities for overseeing NIH and advising the Director of ARPA-H.

We are concerned that if ARPA-H is constituted as a new division, center or institute within NIH, the die will be cast for NIH-directed dollars to be stretched even thinner than they are today.

In FY22, a separate funding stream is likely for ARPA-H and we are grateful for it, but going forward, appropriators would be allocating to a single federal agency. The larger that federal agency, the more difficult it will be to assure needed funding increases year-over-year.

One of the many reasons to avoid supplanting NIH funding is the negative impact on ARPA-H itself. The ability to advance use-driven projects relies on the foundational knowledge uncovered by NIH-supported research.

Other recommendations: Our alliance supports Dr. Lander and Dr. Collins in asserting that ARPA-H should embrace key features of DARPA and ARPA-E, including:

- the hiring flexibility to engage innovators impatient for results regardless of their educational and career trajectory before ARPA-H; and
- the use of contracts, which provide the flexibility to
 - enforce milestones;
 - adapt projects midstream; and
 - expeditiously end projects not seeing results.

Finally, we believe ARPA-H's mission should encompass both health and healthcare innovation. The latter advances health equity and saves lives as surely as biomedical innovation does.

Need, opportunity, and the success of existing ARPA-Hs form a rock solid foundation for ARPA-H.

We stand ready to assist the Administration and Congress as you work to ensure this novel and important innovation incubator joins our nation's R&D ecosystem in 2021.