United States Government Accountability Office

Report to Congressional Committees

February 2024

BIOMEDICAL RESEARCH

Actions Needed to Adopt Collaboration Practices to Address Research Duplication

GAO-24-106757

GAO Highlights

Highlights of GAO-24-106757, a report to congressional committees

February 2024

BIOMEDICAL RESEARCH

Actions Needed to Adopt Collaboration Practices to Address Research Duplication

Why GAO Did This Study

HHS's mission is to enhance the health and well-being of all Americans by, among other things, fostering sound, sustained advances in the sciences. HHS's longstanding agencies—NIH, BARDA, FDA—as well as its newest agency, ARPA-H, fund biomedical research.

The Consolidated Appropriations Act, 2023, includes a provision for GAO to issue a series of reports on potential duplication in HHS's biomedical research and development portfolio. To manage the scope and reporting timeline, this first report focuses on ARPA-H, BARDA, FDA, and NIH as specified in the Act. It (1) describes practices used by the selected HHS agencies to identify and avoid unnecessary research duplication and (2) examines ARPA-H's collaboration and efforts to establish an interagency advisory committee as a potential means to prevent unnecessary research duplication.

To conduct this work, GAO reviewed agency information, and legislation, among other documents. GAO also interviewed agency officials and a non-generalizable selection of non-federal experts in biomedical research.

What GAO Recommends

GAO recommends that ARPA-H finalize the Interagency Advisory Committee charter to clearly define how the participating members agree to share information to avoid ARPA-H's unnecessary research duplication with that of HHS and other federal agencies. HHS neither agreed nor disagreed with the recommendation. GAO maintains the recommendation is warranted.

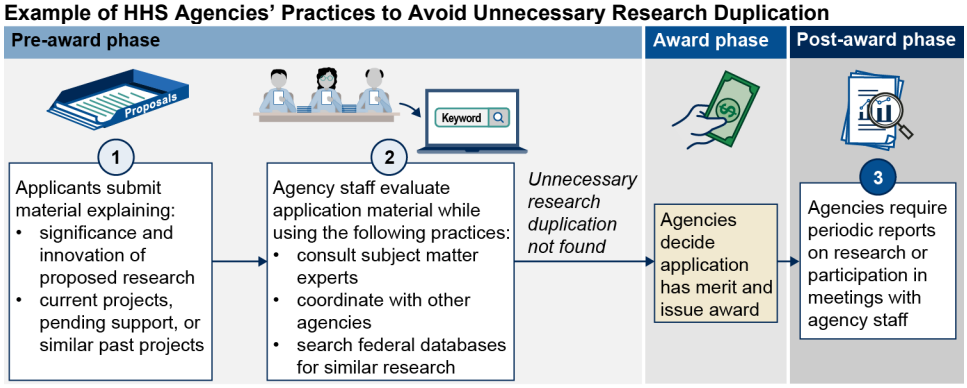
View GAO-24-106757. For more information, contact Candice N. Wright at (202) 512-6888 or wrightc@gao.gov.

What GAO Found

The Department of Health and Human Services (HHS) has long invested in biomedical research. Within HHS, among others, the Advanced Research Projects Agency for Health (ARPA-H), the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Food and Drug Administration (FDA) fund or conduct biomedical research. Each of these four HHS agencies' research activities have the potential for duplication when funding research in common areas.

GAO found the four selected HHS agencies use multiple practices intended to help avoid unnecessary research duplication. These include reviewing project and funding information provided by applicants, consulting with experts and other agencies, and using databases to identify potentially overlapping research (see figure). When evaluating instances of research duplication, agency staff also distinguish between necessary and unnecessary duplication. GAO previously reported that some research duplication is necessary to confirm results or otherwise advance a project or field, whereas unnecessary duplication is research not needed to replicate or complement prior results.

Example of HHS Agencies' Practices to Avoid Unnecessary Research Duplication



Source: GAO analysis of information from Department of Health and Human Services agencies; GAO (illustrations). | GAO-24-106757

In 2022, Congress directed the ARPA-H Director to, among other things, coordinate with other federal departments and agencies to ensure that ARPA-H's research is free of unnecessary duplication and established the ARPA-H Interagency Advisory Committee of eight federal agencies to coordinate efforts, among other functions. Such coordination can be a means for ARPA-H and committee member agencies to share information on their research activities and help ARPA-H avoid unnecessary duplication. ARPA-H officials told GAO that the committee will serve as a forum to identify and address potential research duplication between ARPA-H and these agencies. However, the Committee's draft charter does not mention how the members would collaborate to help ARPA-H identify and avoid funding research duplication. Leading practices for interagency collaboration include identifying shared goals and having documented agreements regarding the collaboration. By finalizing the charter to include members' agreement on collaboration methods to avoid ARPA-H funding unnecessary duplication, ARPA-H will be better positioned to improve the future return on the nation's investment in transformational health research.

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Abbreviations

ARPA-H	Advanced Research Projects for Health
BARDA	Biomedical Advanced Research and Development Authority
DARPA	Defense Advanced Research Projects Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IMPAC II	Information for Management, Planning, Analysis and Coordination II
NIH	National Institutes of Health
QVR	Query, View, Report

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

February 29, 2024

The Honorable Bernard Sanders
Chair
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The federal government has long invested in biomedical research through Department of Health and Human Services (HHS) agencies, including the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Food and Drug Administration (FDA). For example, NIH is a key source of funding for basic research—research that explores the fundamental mechanisms of biology and behavior. Such research facilitates scientific knowledge that informs medical advances. In fiscal year 2022, Congress provided $1 billion for the Secretary of HHS to establish the Advanced Research Projects Agency for Health (ARPA-H).[1] ARPA-H, HHS's newest agency, aims to drive transformational health research innovation and speed medical breakthroughs by tackling ambitious challenges requiring large-scale sustained coordination, including those which span equities across the federal government.

In April 2022, the HHS Secretary formally transferred ARPA-H to NIH.[2] From August 2023 through December 2023, ARPA-H reported that 22 projects were awarded for a total of $387 million. While ARPA-H is intended to complement NIH's existing research portfolio, its funding of

[1]Department of Health and Human Services Appropriations Act, 2022, within Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H, title II, 136 Stat. 441, 465 (2022).

[2]Department of Health and Human Services Transfer of ARPA-H to NIH, 87 Fed. Reg. 23,526 (Apr. 20, 2022), as authorized by Department of Health and Human Services Appropriations Act, 2022, within Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. H, title II, 136 Stat. 441, 465-466 (2022).

research projects in common fields of science has the potential to duplicate funding from elsewhere in NIH and from other HHS agencies conducting biomedical research.

Since March 2011, we have issued annual reports describing areas in which we found evidence of overlap and duplication among federal programs.[3] Research, like programs, also has the potential for overlap and duplication. Overlap exists when multiple agencies or programs have similar goals, engage in similar activities or strategies to achieve them, or target similar populations.[4] Duplication occurs when two or more agencies or programs are engaged in the same activities or provide the same services to the same beneficiaries.[5] In the context of research, overlap and duplication can occur when substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration, among other things.[6] In research, some overlap and duplication may be necessary for building a body of scientific knowledge—a process that requires testing the results of prior work by reproducing the research or replicating its outcomes.[7] However, avoiding and eliminating unnecessarily overlapping and duplicative research can be a means of saving taxpayer dollars and generating more useful scientific outputs.[8] In this report, we use the term "unnecessary research duplication" to mean research that is scientifically unnecessary to replicate or complement prior research results.

[3]*See* Statutory Pay-As-You-Go Act of 2010, Pub. L. No. 111-139, title II, § 21, 124 Stat. 8, 29 (2010), (codified at 31 U.S.C. § 712 note). GAO, *2023 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Billions of Dollars in Financial Benefits*, GAO-23-106089 (Washington, D. C.: Jun. 14, 2023).

[4]See GAO, *Fragmentation, Overlap, and Duplication: An Evaluation and Management Guide*, GAO-15-49SP (Washington, D.C.: Apr. 14, 2015).

[5]GAO-15-49SP.

[6]U.S. Department of Health and Human Services, National Institutes of Health, *NIH Grants Policy Statement* (December 2022).

[7]We have previously stated that to reproduce prior research means to achieve consistent results using the same input data, computational steps, and methods of analysis. To replicate prior research, on the other hand, is to confirm prior results using the same or similar methodology, but different data, to answer the same question. GAO, *Research Reliability: Federal Actions Needed to Promote Stronger Research Practices*, GAO-22-104411 (Washington, D.C.: July 28, 2022).

[8]See GAO, *Agricultural Research: Two USDA Agencies Can Enhance Safeguards against Project Duplication and Strengthen Collaborative Planning*, GAO-13-255 (Washington, D.C.: Apr. 12, 2013).

The Consolidated Appropriations Act, 2023 includes a provision for GAO to issue a series of reports on potential duplication in the agencies contributing to HHS's biomedical research and development portfolio, including ARPA-H, NIH, BARDA, and FDA.[9] We thus selected these four agencies for our review and collectively refer to them as HHS agencies for our purpose.[10] This report, the first in the series, (1) describes practices used by the selected HHS agencies to identify and avoid unnecessary research duplication and (2) examines ARPA-H's collaboration and efforts to establish an interagency advisory committee as a potential means to prevent unnecessary research duplication.

For both objectives, we requested and reviewed internal agency documents from ARPA-H, NIH, BARDA, and FDA related to reviewing and funding biomedical research and the steps the agencies have taken to identify and prevent unnecessary duplication of research projects and programs. We also interviewed officials from these agencies familiar with these steps taken. We conducted a literature search and review of selected sources to identify background information on research duplication.[11] We reviewed publicly available documents such as HHS budget requests, appropriation laws, HHS agencies' research funding announcements, and research funding summaries from fiscal years 2018 to 2022 (the most complete data at the time of our review). We also reviewed ARPA-H research awards that first occurred in fiscal year 2023. Additionally, we reviewed prior GAO reports.

For the first objective, we collected information from officials from the four agencies familiar with the steps taken to identify and prevent unnecessary

[9]Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, within Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, title II, subtitle C, ch. 4, § 2331, 136 Stat. 5627, 5779 (2022) (codified at 42 U.S.C. § 290c(m)).

[10]To manage the scope and reporting timeline of this first report, we only included these agencies. For example, we did not include all federal agencies that fund related research such as HHS's Centers for Disease Control and Prevention.

[11]For our review, we limited our searches to articles published from January 2013 through June 2023 to capture background information on research duplication. We performed searches in databases such as GAO internal publications, the Congressional Research Service, the Congressional Budget Office, inspector general reports, general academic, gray literature, and government resources and services such as Proquest, Ebsco, Dialog, Scopus, and Bloomberg News. We searched for research, investigation, project, program, grant, funding, duplicat*, agency, agencies, HHS, Health and Human Services, ARPA-H, NIH, National Institutes of Health, FDA, Food and Drug Administration, BARDA, and Biomedical Advanced Research and Development Authority.

duplication of research projects and programs and the challenges they face in identifying unnecessary duplication. In addition, we interviewed two experts who had written in published sources regarding research duplication to gather perspectives on the issues regarding research duplication. We identified these experts through our literature search and information from professional association websites. Additionally, we interviewed a non-generalizable selection of one to six subject matter experts in five of the six distinct fields of biomedical research that ARPA-H has identified as areas it expects to fund. We identified these subject matter experts through our literature search and information from professional association websites. ARPA-H may pursue a wide range of research including, but not limited to cancer, diabetes, Alzheimer's disease, osteoarthritis, and infectious disease.[12] We asked these experts for their perspectives regarding research duplication in these topic areas, among other things.

For the second objective, we evaluated ARPA-H actions and policies for collaborating with other federal agencies to identify and prevent unnecessary duplication of research projects and programs. We compared these actions against the leading practices for interagency collaboration which call for agencies to identify shared goals and have documented agreements regarding the collaboration, as appropriate.[13]

We conducted this performance audit from April 2023 to February 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[12]The sixth area is cardiovascular disease. We were unable to schedule interviews with the three selected experts that we identified in this field based on our literature search and review of professional association websites.

[13]See GAO, *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges*, GAO-23-105520 (Washington, D.C.: May 24, 2023).

Background

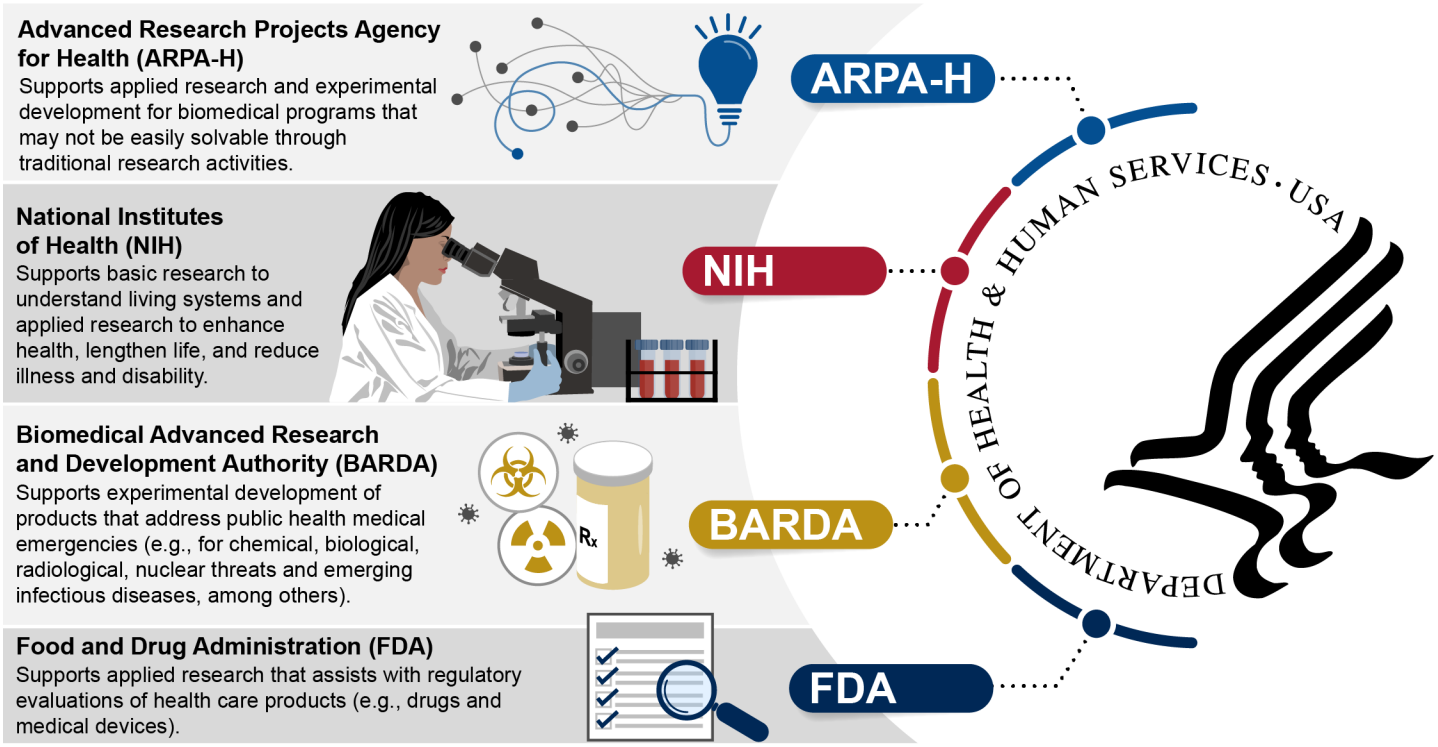
HHS Agencies' Biomedical Research Activities

HHS's mission is to enhance the health and well-being of all Americans by supporting sound, sustained advances in the sciences underlying medicine, public health, and social services. HHS funds different stages of research, including basic research, applied research, and experimental development. These stages of research range from discoveries in the lab to life-saving treatments for patients.[14] Within HHS, the four agencies—ARPA-H, NIH, BARDA, and FDA—that fund or conduct biomedical research have distinct missions and support research that aligns with their mission (see fig. 1). ARPA-H is the newest among these agencies. Its goals, according to the Consolidated Appropriations Act, 2023, include to "foster the development of novel, breakthrough, and broadly applicable capabilities and technologies to accelerate transformative innovation in biomedical science and medicine in a manner that cannot be readily accomplished through traditional Federal biomedical research and development programs or commercial activity."[15]

[14]Basic research is the experimental or theoretical work undertaken to acquire new knowledge of the underlying foundations of phenomena and observable facts. Applied research is the original investigation undertaken in order to acquire new knowledge; however, it is directed primarily towards a specific, practical aim or objective. Experimental development is the creative and systematic work, drawing on knowledge gained from research and practical experience, which is directed to producing new products or processes or to improving existing products or processes. Office of Management and Budget, *Circular A-11 Preparation, Submission, and Execution of the Budget* (Washington, D.C.: Aug. 2022).

[15]Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, within Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, title II, subtitle C, ch. 4, § 2331, 136 Stat. 5627, 5770-5771 (2022) (codified at 42 U.S.C. § 290c(b)(1)).

Figure 1: Types of Biomedical Research Supported by HHS Agencies



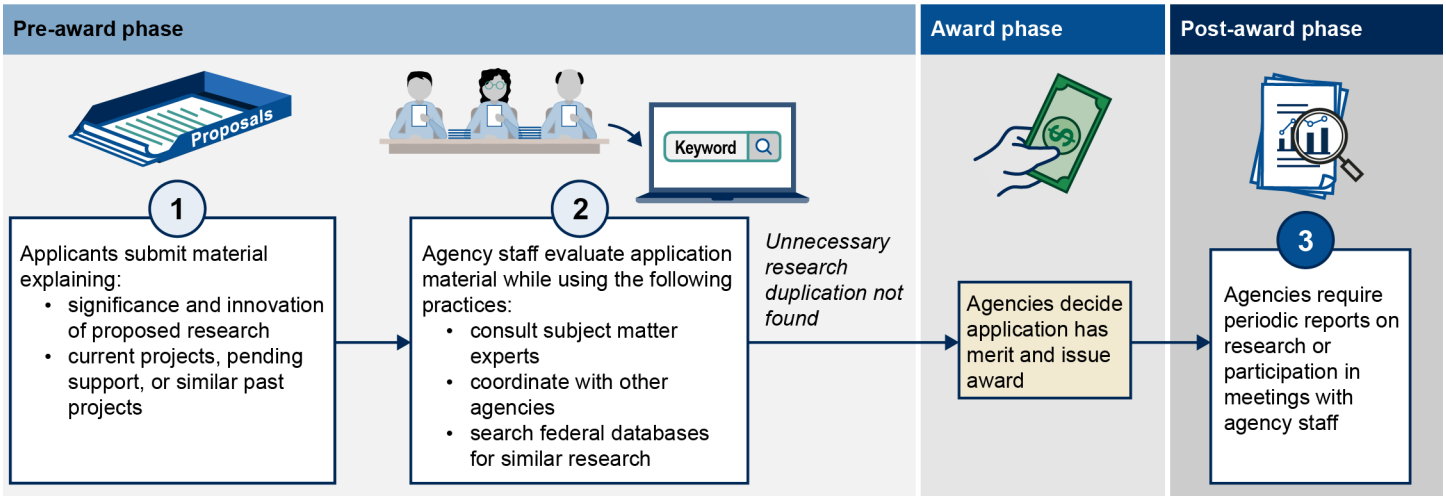
Source: GAO analysis of Department of Health and Human Services (HHS) information; GAO (illustrations); HHS (logo). | GAO-24-106757

HHS Agencies Use Various Practices to Identify and Avoid Unnecessary Research Duplication

We found that staff in the HHS agencies in our review—ARPA-H, NIH, BARDA, and FDA—distinguish between unnecessary and necessary duplication when evaluating identified instances of potential research duplication. To identify unnecessary research duplication, agencies review pre- and post-award information provided by applicants for research funding and consult with subject matter experts and other federal agencies as needed. Additionally, these agencies use federal database search tools when reviewing research applications to award or when designing research programs (see fig. 2).[16] These agencies also employ both shared and agency-specific practices to help identify, and take action to avoid or address, unnecessary research duplication.

[16]In this report, we discuss the steps taken by the agencies prior to funding research as "pre-award" and the steps taken after research funding is awarded as "post-award."

Figure 2: Example of Practices Agencies at the Department of Health and Human Services Use to Help Identify Unnecessary Research Duplication



Source: GAO analysis of information from Department of Health and Human Services agencies; GAO (illustrations). | GAO-24-106757

Agencies Distinguish Between Unnecessary and Necessary Research Duplication

When agency staff identify potential research duplication, they need to distinguish whether the duplication is unnecessary or necessary. As described earlier in this report, research duplication can occur when one or more agencies fund one or more researchers conducting or planning to conduct the same or similar research (see fig. 3).[17] Agency officials told us that they define unnecessary research duplication as inadvertent or deliberate repetition that does not serve the need of verifying conclusions, or that does not contribute significantly to advancing the understanding of a particular research question.

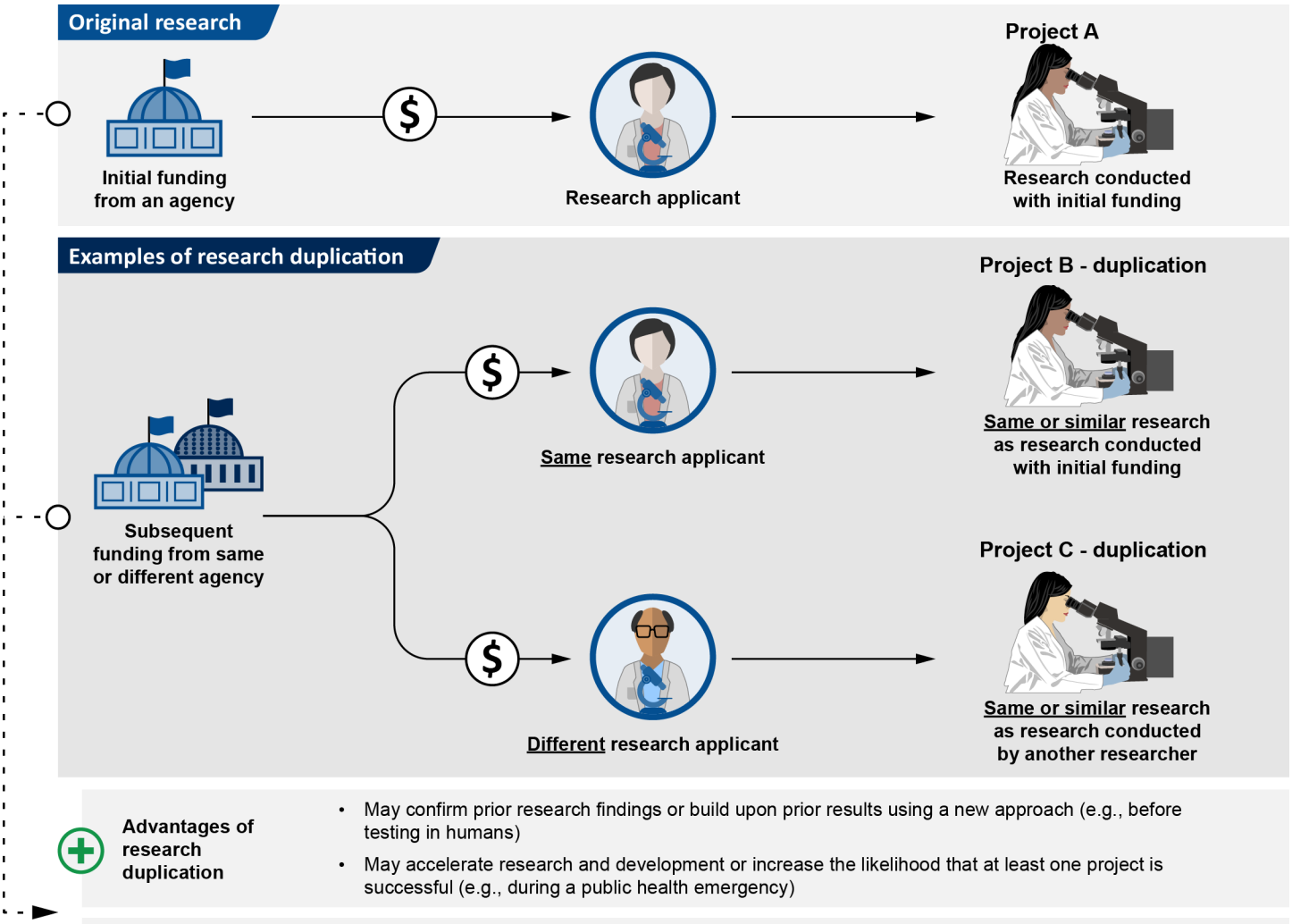
Officials at each of the four agencies told us they would not intentionally fund unnecessary research duplication, but that duplication is sometimes necessary to confirm and build upon the scientific findings of others and move projects and fields forward. For example, ARPA-H officials told us that research duplication may be necessary for researchers to establish consistent results across different laboratories, populations, or settings, and to transition findings into the commercial market. In addition, an agency may intentionally fund multiple researchers to accelerate research and development for a particular purpose. For example, BARDA funded

[17]For the purposes of this report, the term "researchers" refers to individuals associated with a government agency, nongovernmental organization (e.g., universities or companies), or other entity that apply for or receive federal research funding.

multiple entities to conduct vaccine research and development in response to the COVID-19 pandemic (although they used different approaches), in part to increase the likelihood that at least one of the projects would be successful.[18]

[18]In written comments, BARDA officials told us that this example does not represent an instance of necessary duplication, as each vaccine technology that BARDA funded was distinct. However, we believe this instance could be an example of necessary duplication as some efforts used similar approaches and each effort was attempting to develop a safe and effective COVID-19 vaccine.

Figure 3: Examples of Research Duplication and Potential Advantages and Disadvantages



Source: GAO analysis of Department of Health and Human Services (HHS) information; GAO (illustrations). | GAO-24-106757

NIH officials and experts we interviewed explained that deliberate research duplication can be important, in light of issues with lack of

reliability of biomedical research.[19] NIH officials told us they have responded by emphasizing the importance of rigor and reproducibility in research for over a decade, especially for preclinical research in animals because it can serve as the foundation for clinical trials in humans.[20] In addition, subject matter experts in cancer, diabetes, and infectious diseases whom we interviewed told us that insufficient reliability is a big challenge with research generally, and deliberate duplication is sometimes helpful to ensure researchers can rely upon prior research findings. ARPA-H officials told us they consider how much necessary duplication is required to reliably move a project forward and will review the merits of the projects in this context on a case-by-case basis. NIH officials also told us that applicants can propose to replicate certain experiments from prior studies to confirm that they can reproduce the results and build and extend upon those results.

HHS Agencies Require Certain Applicant Information to Help Identify Unnecessary Research Duplication

We found that all HHS agencies in our review—ARPA-H, NIH, BARDA, and FDA—require applicants for research funding to provide information that can help the agencies identify and avoid unnecessary research duplication. Specifically, each agency has written guidance requiring applicants to disclose the following:

- **Significance and innovation of proposed research.** Our review of agency documents shows that staff from all four agencies evaluate an applicant's explanation of how the proposed research is significant and innovative, in part to help identify unnecessary research duplication. Applicants must explain how the proposed research is unique and describe the potential to advance the field. For example, ARPA-H requires applicants to describe the benefits of their proposed approach relative to current state-of-art approaches and compare the proposed research with other ongoing research. This information

[19]We have previously reported that the reliability of biomedical research has come into question following several published investigations. For example, in 2012 an article was published outlining how scientists from Amgen, Inc. had attempted, over the previous decade, to replicate 53 peer-reviewed research studies on blood disorders and cancer that had been deemed "landmark" studies. The scientists reported they could replicate the results from six of the 53 studies when they repeated the experiments. See GAO, *Research Reliability: Federal Actions Needed to Promote Stronger Research Practices*, GAO-22-104411 (Washington, D.C.; July 28, 2022).

[20]For example, in 2003, NIH's National Institute of Neurological Disorders and Stroke launched a new program that provided funding via contracts to carry out independent replication of published studies. See O. Steward et al., "Replication and reproducibility in spinal cord injury research," *Experimental Neurology*, vol. 233 (2012): 597-605.

helps reviewers examine whether the proposed research fills an unmet need for the agency or biomedical research generally.

- **"Other support" and biographical sketches.** Our review of agency documents shows that staff from all four agencies evaluate an applicant's current and pending research to determine whether applicants are already funded, or being considered for funding, for the same work (i.e., "double-dipping"), in part to help identify unnecessary research duplication. For ARPA-H and NIH funding opportunities, applicants must provide a list of all current projects and pending applications (regardless of funding source) for all senior and key personnel, including principal investigators. Additionally, applicants must provide information on the title and research objectives, the amount of time and resources being devoted, and the names of agencies or other parties supporting these projects. For ARPA-H, prospective project directors and principal investigators must provide past research and professional experience, publications, and collaborations and affiliations, among other things. In contrast, NIH encourages but does not require similar information for key personnel and other significant contributors involved in the proposed research.

  For BARDA and FDA, applicants must provide a list of all related activities, current projects, and the last three government-related contracts during the past 3 years that are similar in nature to the work being proposed in the application. Officials from all four agencies told us this information helps reviewers assess whether there is any redundant use of funding and personnel, among other things, which could indicate unnecessary research duplication.

As reflected in figure 2 above, agencies also require certain post-award information from awardees, which agency staff use in part to help identify unnecessary research duplication. We found that all four agencies have requirements for awardees to submit reports (e.g., monthly technical status reports) or participate in meetings with agency staff (e.g., to review technical progress). Officials from all four agencies told us that these updates throughout the life cycle of the award help them identify unnecessary research duplication after the application is funded. For example, NIH requires awardees to submit updates to the "Other Support" section of their application annually, which NIH staff review to identify potential duplication.

Agencies Consult Experts, Other Agencies, and Databases to Identify Unnecessary Duplication

In addition to requiring information from applicants, the four HHS agencies in our review have written guidance or use informal practices to help identify unnecessary research duplication. Agency officials told us that they typically take actions to avoid unnecessary research duplication before research is funded. These pre-award practices include the following, used by multiple HHS agencies:

- **Review by agency staff and subject matter experts.** All four agencies rely on agency staff and experts to help review application documents and provide advice about potential duplication. For example, ARPA-H program managers and subject matter experts (internal and external to the agency) review the documents to help identify similar ongoing research and determine if an applicant has already been funded for similar work. At NIH, in addition to assessments by agency staff, non-federal scientists who have expertise in the relevant scientific discipline and are assigned to review applications in a specific study section may also help to identify when applicants propose duplicative research. BARDA and FDA similarly rely on managers or subject matter experts (both internal and external to the agencies), who review application documents. For example, BARDA relies on federal subject matter experts internal and external to BARDA for application reviews, awareness of related research efforts, and helping to identify unnecessary research duplication.
- **Outreach and coordination with other agencies funding biomedical research.** Officials from all four HHS agencies told us they do some collaboration with other HHS and non-HHS agencies, including through informal and formal mechanisms, that helps to identify unnecessary research duplication.
    - Examples of informal mechanisms of collaboration: ARPA-H officials told us that agency staff regularly meet individually with fellow HHS agencies—including NIH, BARDA, and FDA—to help identify opportunities to collaborate, share research priorities, and identify unnecessary research duplication. In addition, ARPA-H officials told us they are in near-weekly contact with program managers at the Defense Advanced Research Projects Agency (DARPA) to help develop concepts for specific programs.[21]

[21]In addition, BARDA and FDA each have a memorandum of understanding with DARPA to collaborate and coordinate activities. DARPA, which falls under the Department of Defense, invests in various types of transformational research. Such research may include biomedical research to support warfighter readiness, among other things.

- Examples of formal mechanisms of collaboration: NIH officials told us that they meet with the ARPA-H director every other week and engage with ARPA-H staff to help coordinate research efforts. BARDA officials told us they engage regularly, as needed, with other federal partners in the Public Health Emergency Medical Countermeasures Enterprise, to conduct portfolio reviews and provide updates regarding current and future planned research efforts.[22] FDA officials told us they coordinate with other interagency partners, including NIH and BARDA, through workshops.

ARPA-H is developing a more formal coordination strategy among interagency partners. This includes using the ARPA-H Interagency Advisory Committee. Congress established this committee for ARPA-H to coordinate efforts and provide advice and assistance on specific program or project tasks and the overall direction of ARPA-H.[23] ARPA-H officials told us they plan to use the Advisory Committee to, among other things, help identify and avoid unnecessary research duplication among Advisory Committee member entities, which include, among other agencies, NIH, BARDA, and FDA. During our review, the Advisory Committee met for the first time in November 2023 but had not finalized its charter as of

[22]For example, BARDA officials told us that a common practice to avoid unnecessary research duplication is to invite representatives from other agencies who are working on similar research projects to attend periodic contractor team meetings. Officials explained that if potential duplication is identified at those meetings, the representatives will resolve the matter before duplicative work occurs. In addition, the Public Health Emergency Medical Countermeasures Enterprise, or PHEMCE, is an interagency body that, among other things, is intended to coordinate research and development efforts for medical countermeasures for chemical, biological, radiological, and nuclear threats. According to BARDA officials, PHEMCE helps identify and avoid unnecessary research duplication across the federal government. PHEMCE includes senior leaders and experts from NIH, BARDA, FDA, the Centers for Disease Control and Prevention, the Department of Defense, the Department of Veterans Affairs, and other federal agencies.

[23]Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, within Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, title II, subtitle C, ch. 4, § 2331, 136 Stat. 5627, 5780 (2022) (codified at 42 U.S.C. § 290c(p)(1)). Congress directed the ARPA-H Interagency Advisory Committee to include the heads of the following agencies or their designees: NIH, FDA, the Office of the Assistant Secretary for Preparedness and Response (now named the Administration for Strategic Preparedness and Response which includes BARDA), the Centers for Disease Control and Prevention, the Office of the Assistant Secretary of Health, DARPA, the Office of Science of the Department of Energy, and the National Science Foundation, as well as any other agency or office with subject matter expertise that the ARPA-H determines is appropriate to advance ARPA-H programs or projects. *See id.* (codified at 42 U.S.C. § 290c(p)(2)).

December 2023. We discuss the Advisory Committee in more detail below.

- **Federal database search tools.** Officials at ARPA-H, NIH, and FDA told us that agency staff search keywords in federal databases. These searches include administrative information relating to biomedical research applications or funded awards for certain federal agencies—including ARPA-H, NIH, and FDA—to help identify unnecessary research duplication. These federal databases contain information stored in a federal grants management system, known as eRA.[24] Key databases within eRA include:
  - Information for Management Planning, Analysis, and Coordination II (IMPAC II)—which contains unfunded applications and funded awards and is available to agency staff at certain agencies that use eRA—and
  - NIH Research Portfolio Online Reporting Tools Expenditures and Results (RePORTER)—which contains funded awards and is available to all agencies and the public.

IMPAC II has an integrated tool called Query, View, Report (QVR) that allows agency staff to query detailed information they have access to within eRA, including project titles and detailed summaries for research applications and awards. Agency staff can perform on-demand duplication analyses that compare information in eRA against information in a research application. According to agency officials, QVR can help staff identify potential duplication with other agencies funding biomedical

[24]eRA, formerly known as electronic Research Administration is a fee-for-service tool, operated by NIH. Agencies that use eRA include: ARPA-H, NIH, FDA, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, the Agency for Healthcare Research and Quality, the Department of Defense's Congressionally Directed Medical Research Programs, and the Department of Veterans Affairs. ARPA-H makes its funded awards available to the agencies that use eRA. All other agencies that use eRA make their unfunded applications and funded awards available to all agencies that use eRA.

research. For example, ARPA-H officials told us they used QVR to help identify and avoid unnecessary research duplication with NIH.[25]

Agency staff can also use RePORTER to help identify unnecessary research duplication.[26] RePORTER has integrated tools, such as Matchmaker, that allow users to query keywords to find similar researchers and areas of research. For example, ARPA-H officials told us that staff use RePORTER to search keywords for a specific topic to evaluate whether an applicant is potentially double-dipping—that is, receiving duplicate funding for the same research activity.

Agencies Use Agency-Specific Practices to Identify Unnecessary Duplication

Officials from each HHS agency in our review also told us they use agency-specific practices to help ensure that its research portfolio is distinct, and to identify unnecessary research duplication.

ARPA-H officials told us that their agency uses established practices to minimize duplication with research conducted by other entities. Specifically, ARPA-H officials told us that program managers take the following steps for each proposed ARPA-H program before releasing funding announcements soliciting research applications:[27]

- Document how research and development is conducted at present, who does it, and why they think the applicant's research and development will be successful, among other things. This approach,

[25]ARPA-H entered into a memorandum of understanding with NIH dated December 5, 2023, governing the scope and costs of ARPA-H's use of eRA in fiscal year 2024. The previous memorandum of understanding dated June 21, 2023, governed the remainder of fiscal year 2023. ARPA-H staff will be responsible for checking QVR and/or the Dimensions database—a publications data source that tracks how many times and who cited a research article—for all pending awards for potential duplicative efforts. For applications or proposals with potential duplication, ARPA-H staff will work with NIH to assess overlap before determining next steps. In addition, ARPA-H's conclusions of these checks will be documented.

[26]RePORTER allows agencies (and the public) to query high-level information about funded awards to help identify potential unnecessary duplication (see https://reporter.nih.gov/). RePORTER contains funded awards for NIH, FDA, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and the Department of Veterans Affairs. ARPA-H awards will not be available in RePORTER during fiscal year 2024, but the agency makes its current research available on its public-facing website (see https://arpa-h.gov/research-and-funding/programs).

[27]An ARPA-H program may include one or more awardees.

according to ARPA-H, is modeled on a set of principles that DARPA has used for decades.[28]

- Refine program ideas through analyses of public and private sector activity with the help of designated ARPA-H staff;[29] staff at NIH, BARDA, FDA, and other federal agencies; and supplement the analyses with information from the IMPAC II and RePORTER databases and BARDA's websites.[30]
- Formulate each new program to complement, extend, or accelerate work that is already being conducted by the private and public sector so that the ARPA-H program focuses on advances beyond what would happen in the absence of the proposed program.

As noted above, among ARPA-H's congressionally mandated goals is to accelerate transformational innovation in biomedical science and medicine that is not easily solvable through traditional research activities. ARPA-H officials told us that program managers and agency staff expect their approach will inherently avoid unnecessary duplication with other agencies that fund more traditional research activities. Specifically, ARPA-H officials told us ARPA-H is focused on funding research that is high-impact, unique, and complementary to existing work. According to ARPA-H officials, program managers undergo training to help them learn the processes to engage with other biomedical research agencies, and

[28]When proposing a new ARPA-H program, program managers use the ARPA-(H)eilmeier Questions, which are based on the "Heilmeier Catechism," used by DARPA. ARPA-H officials told us ARPA-H specifically uses Heilmeier Question 2 (i.e., *How does this [research and development] get done at present? Who does it? What are the limitations of present approaches?*) and Question 3 (i.e., *What is new about our approach? Why do we think we can be successful at this time?*) as a foundational element during program manager vetting and to support program design.

[29]ARPA-H has an office called the Project Accelerator Transition Innovation Office, or PATIO, that performs landscape analyses and analyzes market trends in part to avoid duplication with the private sector. ARPA-H officials told us that PATIO will provide services to ARPA-H program managers throughout the life cycle of their programs, including to help identify macro trends and accelerate program development.

[30]ARPA-H officials told us their agency relies on BARDA's public websites to examine research that BARDA supports (since BARDA does not use eRA), and this helps ARPA-H staff identify unnecessary research duplication with BARDA. BARDA makes its current research available on these public-facing websites, including BARDA DRIVe (https://drive.hhs.gov/) and others, such as https://medicalcountermeasures.gov/barda/cbrn#portfolio and https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx.

ARPA-H is developing a new program manager orientation that will cover preventing duplication, among other things.[31]

BARDA primarily funds research through contracts and therefore does not have grant application and awards data available through eRA and thus IMPAC II or RePORTER.[32] However, ARPA-H officials told us that ARPA-H is fully cognizant of BARDA's mission and program investment priorities through meetings between ARPA-H and BARDA leadership and by referring to BARDA's websites.

Finally, ARPA-H officials told us that three government reviewers, including individuals internal and external to ARPA-H, review each application, in part to further help ensure ARPA-H efforts are not redundant. According to ARPA-H officials, reviewers must document evidence that there is no unnecessary research duplication before agency officials approve any funding. For example, ARPA-H officials shared an excerpt from a recent assessment they completed pre-award that described that a proposed program was "unique among publicly and privately funded programs," and "due diligence revealed that no other ongoing research exists" for that specific purpose.

NIH requires program and grants management staff to review applications pre-award specifically to determine that there is no unnecessary duplication. In addition to requiring applicants to submit "Other Support" (as described above), NIH instructs applicants to (1) disclose whether the application is being submitted to other funding agencies (and if so, which agencies); and (2) summarize for each individual on the application any potential "overlap" with active or pending research in terms of the science, budget items covered, and the

[31]In December 2023, ARPA-H provided draft training materials for a future program manager training. That training is to emphasize that ARPA-H program managers are required to ensure new programs are designed to fund new and distinct efforts with the help of tools such as RePORTER and QVR to deconflict funded work, among other things.

[32]See FAR 2.101 (defining "contract"); 2 C.F.R. § 200.1 (defining "grant agreement").

individual's time commitment to the research being funded.[33] NIH officials told us that if NIH staff discover unnecessary research duplication during the application phase, they will resolve it prior to making the award, as unnecessary duplication (i.e., scientific, budgetary, or commitment overlap) is not permitted on NIH awards. For example, NIH may contact the applicant's institution to ensure that any unnecessary duplication is removed.

NIH officials told us that they have practices in place for identifying and avoiding unnecessary duplication.[34] For example, NIH noted that it has historically conducted post-award duplication analyses on an ad-hoc basis and provided an example from fiscal year 2018.[35] In that analysis, NIH told us they compared about 47,000 fiscal year 2018 awards to each other and identified six instances of potential duplication. After further analysis, NIH determined that two awards that provided funding to the same investigator represented "scientific overlap," a type of unnecessary research duplication, and NIH subsequently terminated one of the awards. NIH determined this case of unnecessary research duplication was not identified in the pre-award phase because the applicant had inaccurately indicated in the Other Support documentation that there was no overlap among the currently active grants (the onus is on the applicant to provide complete, current, and accurate information or else they may

[33]NIH's Grants Policy Statement lists specific forms of "overlap" that staff look for—including scientific overlap, budgetary overlap, and commitment overlap—which we consider unnecessary research duplication for the purposes of this report. "Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application."

[34]We found in 2017 that NIH had guidance and a formal process in place for grant management staff to review applicants for potential duplication and overlap prior to making a grant award. See GAO, *Grants Management: Selected Agencies Should Clarify Merit-Based Award Criteria and Provide Guidance for Reviewing Potentially Duplicative Awards*, GAO-17-113 (Washington, D.C.; Jan. 12, 2017).

[35]NIH officials told us they have historically done these duplication analyses on an ad-hoc basis, but more recently—due to enhancements in processing speed and refinements to their algorithm—they are formulating a timeline to conduct these post-award analyses on a regular schedule.

incur penalties).[36] In addition, NIH officials told us they consider NIH's internal controls to be robust based on a 2020 HHS inspector general report that found NIH had effective internal controls for ensuring that award recipients did not receive duplicate funding.[37]

BARDA officials told us that the agency's research mission is distinct within HHS, which helps the agency avoid unnecessary research duplication with agencies that are focused on other biomedical research activities. Specifically, BARDA officials told us they normally support research that helps to prepare for certain public health threats, and they focus specifically on the advanced clinical development, regulatory approval, manufacturing, and procurement of relevant medical countermeasures. ARPA-H officials told us they may invest in research that leads to improved medical countermeasures, including those that BARDA might support, but ARPA-H believes its coordination with BARDA is sufficient to avoid unnecessary duplication. BARDA officials also told us that the agency's contracting officer's representatives[38] receive training that underscores the importance of eliminating all funding overlap among agencies.

In addition, agency documents and officials from BARDA indicated that the agency uses technical evaluation panels. These panels are composed of subject matter experts (internal and external to BARDA) that evaluate research applications based on the extent that they fill an unmet programmatic need and have the potential to offer revolutionary increases in capability, among other things.

[36]Based on the low frequency of identified overlap in the duplication analysis, NIH did not believe it was necessary to change any policies or practices; however, NIH has issued guidance in recent years to enhance Other Support reporting based in part on government-wide concerns about a lack of sufficient disclosure. NIH issued a notice in July 2019 to remind applicants, among other things, of their obligations to correctly report information in Other Support documents. Further, in May 2021 NIH enhanced the Other Support reporting requirements by adding a requirement to submit supporting documentation for all foreign activities and resources reported in Other Support, and an immediate notification requirement for recipient organizations that discover that senior or key personnel on an active NIH grant failed to disclose Other Support information.

[37]See HHS Office of Inspector General, *The National Institutes of Health Has Controls to Mitigate the Risk that Grantees Receive Duplicate Grant Funding*, A-02-19-02002 (Mar 2020). The audit period for this inspector general report was October 2017 through September 2018.

[38]A contracting officer's representative is a person designated and authorized in writing by the contracting officer for a particular contract to perform specific technical or administrative functions. FAR 2.101.

FDA officials told us that the agency focuses primarily on regulatory science, which covers different areas of biomedical research than other agencies, and the risk of unnecessary research duplication is therefore low.[39] Specifically, FDA officials told us they are focused on funding research that can help inform their regulatory decision-making, which is a different perspective than other biomedical research agencies. ARPA-H officials told us that they cannot predict whether they would fund regulatory science, but ARPA-H anticipates working closely with FDA to ensure they avoid unnecessary duplication.

FDA officials told us they ensure that funded applications align with the specific research needs of the agency, including those described in an updated 2022 report that outlines specific focus areas and topics of interest across FDA.[40] FDA also uses technical evaluation panels, composed of FDA staff and internal subject matter experts—and, at times, external experts—that evaluate research applications based on the extent to which they address an unmet need in regulatory science and have the potential to offer revolutionary increases in capability, among other things.

While officials from each HHS agency in our review stated they have sufficient policies and practices in place to mitigate the risk of unnecessary research duplication, two HHS agencies—NIH and ARPA-H—identified specific challenges to avoiding such duplication.

NIH officials told us that their biggest challenge is identifying potential research duplication with awards made from sources outside NIH and not listed in eRA. This includes awards made by agencies, such as BARDA, that do not use IMPAC II or RePORTER and awards funded by private or foreign entities. NIH officials told us that agency staff cannot perform duplication analyses on awards made by agencies using databases other than IMPAC II or RePORTER or funded by private or foreign entities. However, NIH officials told us that information provided in application documents, including Other Support, contains award information from other agencies and private

[39]FDA defines regulatory science as the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of some FDA-regulated products.

[40]See FDA, "2022 Advancing Regulatory Science at FDA: Focus Areas of Regulatory Science (FARS)," https://www.fda.gov/media/161381/download, accessed October 26, 2023.

or foreign funders, which helps NIH identify and avoid unnecessary research duplication with those entities.

ARPA-H officials told us they face challenges with identifying current research findings, which are always changing and advancing. Further, they added that limited visibility and coordination among various funding agencies makes it difficult for ARPA-H to have a comprehensive view of ongoing biomedical research. ARPA-H officials told us that obtaining such a complete picture requires them to conduct direct outreach to agencies that do not share research information in federal databases (e.g., BARDA). In addition, ARPA-H officials identified challenges in assessing potential research duplication with the private sector because private entities may not fully disclose proprietary or confidential information about ongoing research including funding provided to researchers.

ARPA-H Has Not Finalized Its Interagency Committee Charter to Address Duplication

To help address the challenges ARPA-H described above, ARPA-H officials told us they plan to establish more effective collaboration within HHS and other federal agencies such as DARPA. They intend to improve data sharing to help better identify and avoid potential unnecessary research duplication. Officials from NIH, BARDA, and FDA also told us that they plan to improve ongoing communication with ARPA-H to identify and avoid unnecessary research duplication. For example, BARDA officials told us that BARDA anticipates signing a memorandum of understanding with ARPA-H and being involved in portfolio exchanges. Similarly, FDA officials told us FDA plans to have future meetings with ARPA-H to discuss research priorities and shared interests. ARPA-H officials told us they had been in discussions with NIH about how ARPA-H can best use eRA and associated tools going forward. In December 2023, ARPA-H entered into a memorandum of understanding with NIH governing the scope and costs of its use of eRA in fiscal year 2024. This memorandum indicated that ARPA-H data in eRA will be available to other agencies that use QVR, and that ARPA-H staff will reach out to NIH staff if they identify potential duplicative efforts. Additionally, to better identify potential research duplication with private and foreign funding sources, ARPA-H officials told us they may, if ARPA-H staff deems it necessary, require additional reporting from awardees to update ARPA-H on the funding sources they receive during the course of their research.[41]

[41]ARPA-H officials told us that awardees should disclose all sources of funding for their research project, including private and foreign sources of funding, in the pre-award phase.

Advanced Research Projects Agency for Health (ARPA-H) Interagency Advisory Committee

The Consolidated Appropriations Act, 2023 established the ARPA-H Interagency Advisory Committee to coordinate efforts and provide assistance on specific program or project tasks and the overall direction of ARPA-H.

Congress directed the Advisory Committee to include the heads of the following agencies or their designees:

- The National Institutes of Health
- The Centers for Disease Control and Prevention
- The Food and Drug Administration
- The Office of the Assistant Secretary for Preparedness and Response (now named the Administration for Strategic Preparedness and Response), which includes the Biomedical Advanced Research and Development Authority
- The Office of the Assistant Secretary of Health
- The Defense Advanced Research Projects Agency
- The Office of Science of the Department of Energy
- The National Science Foundation

Additionally, Congress directed ARPA-H to include any other agency or office with subject matter expertise that the agency determines is appropriate to advance ARPA-H programs or projects.

Source: Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, within Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, title II, subtitle C, ch. 4, § 2331, 136 Stat. 5627, 5780-5781 (2022) (codified at 42 U.S.C. § 290c(p)(1)-(2)). | GAO-24-106757

Another avenue of collaboration is the ARPA-H Interagency Advisory Committee. The Consolidated Appropriations Act, 2023, dated December 29, 2022, calls for the ARPA-H Director to, among other things, coordinate with other relevant federal departments and agencies to facilitate data and information sharing and ensure that ARPA-H's research is free of unnecessary duplication.[42] Further, the Act established the Advisory Committee to coordinate efforts and provide assistance on specific program or project tasks and the overall direction of ARPA-H. The membership of the Advisory Committee includes the heads of the four HHS agencies, as well as other agencies within and outside of HHS.[43] The Act does not mention the avoidance of duplication as a specific purpose of the Advisory Committee, but ARPA-H officials told us that the committee will serve as a forum to identify and address potential research duplication between ARPA-H and these agencies. The committee's draft charter provided to GAO in December 2023, says it will serve as a forum to "harmonize government-wide efforts in health innovation."

From August 2023 through December 2023, ARPA-H reported that 22 projects were awarded for a total of $387 million. However, ARPA-H began funding this research before the ARPA-H Interagency Advisory Committee met. The committee did not hold its first meeting until November 2023. ARPA-H officials told us they met with members of the Advisory Committee individually to help identify and avoid unnecessary research duplication in the pre-award phase on all their recent awards. ARPA-H plans to convene the full Advisory Committee on at least a biannual basis and provide members ongoing updates regarding ARPA-H activities on an ongoing basis between meetings.

As of December 2023, when we provided a draft of this report to agencies for comment, its charter had not been finalized and did not mention duplication. For example, the draft charter and November 2023 meeting

[42]Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, within Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, title II, subtitle C, ch. 4, § 2331, 136 Stat. 5627, 5772 (2022) (codified at 42 U.S.C. § 290c(c)(4)(E).

[43]Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, within Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, div. FF, title II, subtitle C, ch. 4, § 2331, 136 Stat. 5627, 5780-5781 (2022) (codified at 42 U.S.C. § 290c(p)(1)-(2)).

materials that were provided to us indicated that the committee had not yet agreed on any shared goals—including the agency's stated intention of identifying and addressing potential research duplication between HHS agencies and other agencies. The meeting materials stated that the charter would be finalized and sent back to committee members.

In February 2024, in responding to a draft of this report, ARPA-H provided an updated charter that was revised to state that the interagency committee would serve as "a forum to minimize inefficiencies that can arise from duplication of effort." The charter further states that ARPA-H will share information on the findings from its efforts to avoid unnecessary duplication in research portfolios across the federal government. However, the updated charter is unsigned and not dated. Thus, it falls short of being finalized and reflecting the agreement of all committee members.

As we previously reported, it is important for agencies that fund research on topics of common interest to share information on each other's activities to reduce unnecessary research duplication.[44] Furthermore, leading practices for interagency collaboration call for agencies to identify shared goals and have documented agreements regarding the collaboration, as appropriate.[45] In the updated charter provided to us in February 2024 in response to the draft report, ARPA-H had not incorporated these leading practices in its Advisory Committee charter. For example, according to ARPA-H officials, the committee would be an effective way to monitor and prevent unnecessary research duplication. However, ARPA-H has not documented how the Advisory Committee members would be tasked to collaborate and share information to proactively identify potential areas of their agencies' research duplication with ARPA-H. Finalizing the Advisory Committee's charter to identify and document agreement to share data and information about ongoing and planned biomedical research will better position ARPA-H and the other committee member agencies to meaningfully reduce the potential for unnecessary duplication. Further, documenting such agreements in the charter will have the additional benefit of ensuring that commitments to identify unnecessary duplication will be sustained as agency representation on the committee changes.

[44]See GAO, *2012 Annual Report: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue,* GAO-12-342SP (Washington, D.C.: Feb 28, 2012).

[45]GAO-23-105520.

Conclusions

Funding similar research on the same topic is sometimes appropriate and necessary, for example, for the purposes of replicating or corroborating prior research results. The four HHS agencies included in our review that conduct biomedical research have the potential for duplication when funding research in common areas. ARPA-H has established practices to identify and avoid unnecessary duplication. It has also identified various challenges including identifying projects funded by other HHS agencies. While ARPA-H has taken steps to coordinate with individual committee member agencies, it began funding research without the collective input of the ARPA-H Interagency Advisory Committee and could be at risk of supporting unnecessary duplication. By fully standing up the Advisory Committee—such as finalizing its charter to document members' agreement for collaboration and sharing information—ARPA-H would better position the committee to meaningfully reduce the potential for ARPA-H's unnecessary research duplication. By bringing together funding agencies to focus on the risk of unnecessary duplication, ARPA-H and its Advisory Committee have the potential to save taxpayer dollars and improve the future return on the nation's investment in transformational health research.

Recommendation for Executive Action

The Director of ARPA-H should finalize the ARPA-H Interagency Advisory Committee's charter to clearly define how the participating members agree to share information to avoid ARPA-H's unnecessary research duplication with that of HHS and other federal agencies.

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. HHS's comments are reproduced in Appendix I. HHS also provided technical comments, which we incorporated into the report as appropriate. In its comments, HHS did not agree or disagree with the recommendation but stated that it considers the recommendation to be closed/implemented.

In its comments on the draft report, ARPA-H noted that the Act establishing the ARPA-H Interagency Advisory Committee does not include avoiding duplication. We acknowledged this in the draft report provided to HHS for comment. However, the Act calls for the interagency committee to coordinate efforts, among other things. The Act also calls for the ARPA-H Director to, among other things, coordinate with other relevant federal agencies to facilitate data and information sharing and ensure that ARPA-H's research is free of unnecessary duplication. Further, during our review, ARPA-H officials told us that the committee will serve as a forum to identify and address potential research duplication between ARPA-H and these agencies. Taken together, the interagency committee can be an effective mechanism to ensure

ARPA-H's coordination with other federal agencies will minimize the potential for unnecessary research duplication.

Originally, our draft report noted that the ARPA-H Interagency Advisory Committee charter had not been finalized and did not address duplication. Specifically, the draft charter did not mention the committee's shared goals or plans to share information to proactively identify potential areas of member agencies' research that could duplicate ARPA-H's research activities. In responding to the draft report, HHS shared a revised charter on February 2, 2024. The revised charter states that an objective of the committee is to serve as a forum to harmonize government-wide efforts in health innovation and minimize inefficiencies that can arise from duplication of effort. Further, the charter states that ARPA-H will present in this forum the findings of the established practices it is using to prevent unnecessary duplication of research portfolios. However, the revised charter provided to us does not fully meet the intent of our recommendation. For example, the revised charter does not clearly define how participating members agree to share information to avoid ARPA-H's unnecessary research duplication with other agencies. Additionally, the revised charter provided to us was unsigned and not dated. Thus, it cannot be considered finalized and agreed to by the Advisory Committee members. We incorporated updates in the report to reflect the revised charter.

ARPA-H noted that it considers the recommendation made in our draft report has been implemented, in light of its revisions to the interagency charter. We maintain that the recommendation to incorporate plans for committee members to share information in a finalized charter is still warranted to better ensure such activities occur and will be sustained over time including in the event committee members change.

We provided a draft of this report to HHS for review and comment.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties.

If you or your staffs have any questions about this report, please contact me at (202) 512-6888 or wrightc@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix II.

Candice N. Wright
Director, Science, Technology Assessment, and Analytics

Appendix I: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

February 2, 2024

Candice N. Wright
Director, Science, Technology Assessment, and Analytics
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Wright:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"BIOMEDICAL RESEARCH: Actions Needed to Adopt Collaboration Practices to Address Research Duplication" (GAO-24-106757).**

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT – BIOMEDICAL RESEARCH: ACTIONS NEEDED TO ADOPT COLLABORATION PRACTICES TO ADDRESS RESEARCH DUPLICATION (GAO-24-106757)

The Advanced Research Projects Agency for Health (ARPA-H) appreciates the review conducted by the Government Accountability Office (GAO) and the opportunity to provide clarifications on this draft report. ARPA-H especially appreciates the finding on page 22, which accurately states "*ARPA-H has established practices to identify and avoid unnecessary duplication.*"

ARPA-H respectfully submits the following general comment.

GAO Recommendation 1
The Director of ARPA-H should finalize the ARPA-H Interagency Advisory Committee's charter and clearly define goals and plans to avoid ARPA-H's unnecessary research duplication with that of participating members of HHS and other federal agencies.

ARPA-H Response
ARPA-H considers the recommendation as closed-implemented.

While the statutory remit for the ARPA-H Interagency Advisory Council does not include avoiding duplication, ARPA-H has updated the Charter for the ARPA-H Interagency Advisory Committee to require information sharing on the extensive work already being done throughout the ARPA-H program lifecycle to prevent research duplication that has been detailed extensively in this draft report.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Candice N. Wright at (202) 512-6888 or WrightC@gao.gov

Staff Acknowledgments

In addition to the contact named above, Hayden Huang (Assistant Director), George Depaoli (Analyst-in-Charge), Shannon Brooks, Cory Gerlach, and Kristin Hook made key contributions to this report. Caroline Gross, Anika McMillon, Ben Shouse, and Amber Sinclair also contributed.

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Strategic Planning and External Liaison

Stephen J. Sanford, Managing Director, spel@gao.gov, (202) 512-4707
U.S. Government Accountability Office, 441 G Street NW, Room 7814,
Washington, DC 20548