



441 G St. N.W.
Washington, DC 20548

Accessible Version

July 23, 2024

The Honorable Tammy Baldwin
Chair
The Honorable Shelley Moore Capito
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Robert Aderholt
Chair
The Honorable Rosa DeLauro
Ranking Member
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
Committee on Appropriations
House of Representatives

National Institute on Aging: Leading Project Management Practices Are Important for Large-Scale Health Data Efforts

More than 6 million Americans are currently living with Alzheimer’s disease, and it is predicted that more than 13 million will be living with the disease by 2060. Alzheimer’s disease is currently the seventh leading cause of death in the United States. This disease slowly destroys brain function, leading to cognitive decline (e.g., memory loss, language difficulty, poor executive function), behavioral and psychiatric disorders (e.g., depression, delusions, agitation), and declines in functional status (e.g., ability to engage in activities of daily living and self-care).

In March 2023, to enhance the research on aging and dementia, the National Institute on Aging (NIA) began soliciting applications for the development of the Real-World Data Platform (RWDP).¹ This platform was intended to be a large-scale health research project aimed at improving research on Alzheimer’s disease and related dementias (ADRD) through compiling and analyzing real-world data and using emerging technologies such as machine learning and artificial intelligence.² In May 2023, you had asked us to review how NIA is managing RWDP.

¹According to NIA, real-world data is data collected during routine care in real-world settings as opposed to data collected within clinical trials.

²Machine learning is a family of statistical and mathematical modeling techniques that uses a variety of approaches to automatically learn and improve the prediction of a target state, without explicit programming. See: GAO, *Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning in Drug Development*, [GAO-20-215SP](#) (Washington, D.C.: Dec. 20, 2019). Artificial intelligence, or AI, in general, refers to computer systems that can solve problems and perform tasks that have traditionally required human intelligence and that continually get better at their assigned tasks. AI is described as a transformative technology with applications ranging from medical diagnostics and precision agriculture to advanced manufacturing and autonomous transportation, to national security and

However, during the course of our work, NIA decided not to fund the project in April 2024. NIA officials stated that this decision was, in part, due to the presence of other federal large-scale health data efforts and an increased number of proposed solutions in the field of ADRD research. This report (1) examines the extent to which NIA implemented leading practices for the cost estimate and project management for RWDP and (2) describes NIA's decision not to fund RWDP and lessons learned.

To answer our first objective, we analyzed key NIA documents related to planning and managing the RWDP project (e.g., cost estimates and policies) and compared these against National Institutes of Health (NIH) guidance and leading practices for cost estimating and project management, which we selected based on their relevance to the project.

To analyze NIA's efforts to fully estimate cost for RWDP, we assessed and verified NIA's cost documentation against cost estimating best practices identified by our *Cost Estimating and Assessment Guide*.³ These leading practices map to the four characteristics of a high-quality, reliable cost estimate—comprehensive, well-documented, accurate, and credible. Specifically, we analyzed cost documentation from the request for applications, a cost estimate summary, a cost estimate development spreadsheet, and personnel effort calculations for RWDP. For each of the four characteristics of a reliable cost estimate, we assessed the evidence against the leading practices to determine whether NIA fully, substantially, partially, minimally or did not meet the leading practices.

We also selected key leading practices from four practice areas related to project management identified by the ISACA Capability Maturity Model® Integration (CMMI®).⁴ The selected practice areas were (1) governance, (2) planning, (3) requirements development and management, and (4) risk management. Based on our professional judgement, we selected the simplest set of practices within these areas to address the full intent of each practice area. We then assessed and verified NIA responses and documentation against the selected CMMI leading practices for the relevant practice areas. Specifically, we reviewed the request for applications, request for information, NIH policies, the staffing plan, and NIA written responses to our question sets. For each of the selected practice areas related to project management, we assessed the evidence against the leading practices from those practice areas to determine whether NIA fully, substantially, partially, minimally, or did not implement the best practices.

To answer our second objective, we compiled and summarized NIA documentation relevant to the decision not to fund RWDP, including lessons learned. Additionally, we interviewed NIA and NIH officials responsible for the project.

We conducted this performance audit from June 2023 to July 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

defense. See: GAO, *Artificial Intelligence: Agencies Have Begun Implementation but Need to Complete Key Requirements*, [GAO-24-105980](#) (Washington, D.C.: Dec. 12, 2023).

³GAO, *Cost Estimating and Assessment Guide: Best Practices for Developing and Managing Program Costs*, [GAO-20-195G](#) (Washington, D.C.: Mar. 12, 2020).

⁴ISACA, *CMMI Model V3.0* (Apr. 6, 2023). CMMI Model and ISACA ©[2023] All rights reserved. Used with permission.

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.

Background

Upon the enactment of the National Alzheimer's Project Act in 2011, the Department of Health and Human Services (HHS) began to coordinate activities related to ADRD research across federal agencies.⁵ As part of these efforts, NIA, a component institute of HHS's NIH, was designated as the lead component for researching and understanding the aging process and ADRD. The institute receives leadership and direction from NIH to complete its goals and mission. NIA's goal is to understand the nature of aging, the aging process, and diseases and conditions associated with growing older, one of which is ADRD.⁶

According to NIA, limited access to real-world data is one of the most pervasive and costly issues in ADRD research. Real-world data are related to patient health status and/or the delivery of health care from a variety of sources, such as electronic health records, medical claims, product and disease registries, and patient-generated information, including from in-home-use settings and mobile devices.

As previously mentioned, NIA proposed an initiative called RWDP to improve ADRD research through a platform that facilitates compiling and analyzing real-world data. Specifically, NIA's goals for RWDP were to

- create a centralized data warehouse for integrating data from sources such as electronic health records, health and pharmacy claims, sensors, and birth and death databases;
- represent an estimated 80 percent of the ADRD patient population, a range of adult cohorts, and the racial and ethnic diversity of the United States;
- define goals and objectives for using real-world data to address health disparities in the United States through recruitment innovation, community engagement, and improved capacity for conducting research on more inclusive and diverse populations; and
- facilitate partnerships across various health providers, including pharmacies, for recruiting inclusive and diverse populations for NIA-funded studies.

The data platform was to be funded through a cooperative agreement, which NIH officials noted is a support mechanism used when there would be substantial federal scientific or programmatic involvement.⁷ NIH defines "substantial involvement" as the institute's scientific or program staff providing technical assistance, advice, coordination, and other functions beyond the usual level of programmatic and scientific stewardship of grants. According to NIH policy, under a cooperative agreement, NIA should support and stimulate the award recipient's activities by being involved in and otherwise working jointly with the award recipients in a

⁵Pub. L. No. 111-375, Jan. 4, 2011 (42 U.S.C. § 11225)

⁶NIA outlined its goals and framework for researching and understanding the aging process in its *Strategic Directions for Research, 2020-2025*. National Institute on Aging, *National Institute on Aging: Strategic Directions for Research, 2020-2025*, (Bethesda, MD: 2020).

⁷According to 2 CFR Part 200, when specifying statutory requirements for the award mechanism of cooperative agreements, the "Federal Award Information" section of the award mechanism either should describe the "substantial involvement" that the federal awarding agency expects to have or should reference where the potential applicant can find that information.

partnership role.⁸ As such, under a cooperative agreement, the dominant role and prime responsibility resides with the award recipients for the project as a whole, although specific tasks and activities may be shared among the award recipient and NIA.⁹

NIA estimated the total cost for the project to be \$312 million over 6 years.¹⁰ NIA intended to commit \$50 million per year to the RWDP awardee from fiscal year 2024 through fiscal year 2029. Additionally, the National Institute of Neurological Disorders and Stroke intended to contribute \$2 million per year from before the end of fiscal year 2024 through fiscal year 2029.

On March 13, 2023, NIA published a request for applications for RWDP. The request for applications identified the intended development and structure for the data platform and contained, among other things, information about the award and project funding, eligibility information for applicants, and application review information. The application period for the request for applications opened on June 30, 2023 and closed on July 31, 2023. According to NIA officials, in November 2023, NIA began its scientific merit review of all RWDP applications submitted.

In March 2024, Congress addressed NIA's development of RWDP with NIH's fiscal year 2024 appropriation. Specifically, the *Explanatory Statement Regarding the Further Consolidated Appropriations Act, 2024* stated that due to preliminary concerns raised by GAO about the reliability of RWDP's cost estimate, Congress urged NIA to pause funding for the award until issuance of this report.¹¹ Further, the Explanatory Statement directed NIA to report progress on the development of the data platform to the Senate and House Appropriations committees every 30 days.

However, as noted earlier, NIA decided not to fund the RWDP project in April 2024. NIA's reasons for this decision are discussed in greater detail later in this report.

NIA Did Not Fully Implement Key Leading Practices for Cost Estimating and Project Management for RWDP

Prior to its decision not to fund RWDP, we found that NIA did not fully implement key leading practices for the data platform's cost estimate or project management (see table 1).

⁸National Institutes of Health, *NIH Policy Manual 54815 – Implementation of Cooperative Agreements*. (Bethesda, MD: 2009).

⁹Cooperative agreements are a form of grants with a greater level of involvement between the federal agency and the awardee in carrying out the activity contemplated in the agreement, including developing methodologies and reporting outcomes. See, e.g., 31 U.S.C. § 6305; 2 CFR 200.1.

¹⁰According to NIA, the estimate included indirect costs incurred by the federal government to complete the RWDP project. Per the NIH Grants Policy Statement, facilities and administrative costs, or indirect costs, are necessary costs incurred by a recipient for a common or joint purpose benefitting more than one cost objective.

¹¹H.R. Rep. No. 170-51 (Book II) (2024); Pub. L. No. 118-42 (H.R. 4366), March 8, 2024.

Table 1: Extent to Which NIA Implemented Key Leading Practices for the Real-World Data Platform’s Cost Estimate and Project Management

Key Leading Practices	Assessment
Characteristics of a reliable cost estimate (comprehensive, well-documented, accurate, and credible)	minimally implemented
Project management practice areas (governance, planning, requirements development and management, and risk management)	minimally implemented

Legend: ● – Fully implemented – NIA provided complete evidence that satisfies the entire criteria; ● - Substantially implemented – NIA provided evidence that satisfies a large portion of the criteria; ● - Partially implemented – NIA provided evidence that satisfies about half of the criteria; ● - Minimally implemented – NIA provided evidence that satisfies a small portion of the criteria; ○ – Not implemented – NIA provided no evidence that satisfies any of the criteria.

Source: GAO analysis of National Institute on Aging (NIA) information. | GAO-24-106886

NIA’s Cost Estimate for the Data Platform Minimally Met the Four Characteristics of a Reliable Cost Estimate

GAO’s *Cost Estimating and Assessment Guide* provides leading practices associated with a reliable cost estimate to enable government programs to better estimate and manage their costs for improved program management and execution.¹² According to this guide, the four characteristics of a reliable cost estimate are that it is comprehensive, well documented, accurate, and credible.

NIA’s cost estimate for RWDP, which was anticipated to be \$312 million over 6 years, minimally met the four characteristics of a reliable cost estimate. For example, while some cost estimate documentation for the data platform was updated before the request for applications was solicited, the documentation did not include all costs, describe how the current estimate was developed, or provide sufficient information about the source data used. Table 2 summarizes our assessment of RWDP’s cost estimate compared against GAO’s *Cost Estimating and Assessment Guide*.

¹²[GAO-20-195G](#).

Table 2: Extent to Which NIA’s Cost Estimate for the Real-World Data Platform (RWDP) Met the Characteristics of a Reliable Cost Estimate

Characteristic	Leading practice	Analysis	Overall assessment
Comprehensive	<ul style="list-style-type: none"> Includes all life cycle costs Is based on a technical baseline description Is based on a work breakdown structure (WBS) Documents all cost-influencing ground rules and assumptions 	<ul style="list-style-type: none"> NIA’s estimate did not include all possible life cycle costs, such as those for National Institutes of Health management and staff or other workshop expenses. NIA could not provide documents related to a technical baseline. Costs were not broken down into specific elements of the project in a WBS. It was not evident that all ground rules and assumptions had been documented or that risks associated with assumptions had been identified. 	minimally implemented
Well-documented	<ul style="list-style-type: none"> Shows the source data used, the reliability of the data, and the estimating methodology used to derive each element’s cost Describes how the estimate was developed so that a cost analyst unfamiliar with the program could understand what was done and replicate it Discusses the technical baseline description and ensures the data in the technical baseline are consistent with the cost estimate Provides evidence that the cost estimate was reviewed and accepted by management 	<ul style="list-style-type: none"> NIA’s documentation did not provide sufficient information about source data used. NIA’s documentation did not sufficiently describe how the cost estimate was developed. NIA did not have a technical baseline description, so officials could not discuss how it was consistent with the cost estimate data. It was not evident that NIA management was presented with sufficient information about how the cost estimate was constructed to determine the estimate’s completeness and quality. 	minimally implemented
Accurate	<ul style="list-style-type: none"> Is based on a model developed by estimating each WBS element using the best methodology from the data collected Is adjusted properly for inflation Contains few, if any, minor mistakes Is regularly updated to ensure it reflects program changes and actual costs^a Documents, explains, and reviews variances between planned and actual costs^a Is based on a historical record of cost estimating and actual experiences from other comparable programs 	<ul style="list-style-type: none"> NIA did not provide a cost model showing the development of the \$312 million commitment for RWDP. The primary estimating methodology used was subject matter expertise; however, overuse of this subjective methodology may introduce bias. Application of inflation to the cost estimate was not evident. Although NIA lacked a cost model for the estimate, the limited documentation NIA prepared contained few mistakes. It was not clear if the cost estimate was based on a historical record of cost estimating. 	minimally implemented

Characteristic	Leading practice	Analysis	Overall assessment
Credible	<ul style="list-style-type: none"> Includes a sensitivity analysis Includes a risk and uncertainty analysis Employs cross-checks on major cost elements to validate results Includes an independent cost estimate 	<ul style="list-style-type: none"> NIA had not performed a sensitivity analysis. NIA had not performed a cost risk and uncertainty analysis. It was not evident that NIA performed cross-checks on major cost elements. It was not evident that NIA had performed an independent cost estimate. 	minimally implemented

Legend: ● – Fully met – NIA provided complete evidence that satisfies the entire criterion; ● – Substantially met – NIA provided evidence that satisfies a large portion of the criterion; ◐ - Partially met – NIA provided evidence that satisfies about half of the criterion; ◑ - Minimally met – NIA provided evidence that satisfies a small portion of the criterion; ○ – Not met – NIA provided no evidence that satisfies any of the criterion

Source: GAO analysis of National Institute on Aging (NIA) information. | GAO-24-106886

^aWe did not review this practice because NIA stated that nothing had been expended and the award had not been made.

NIA Did Not Fully Implement Key Project Management Leading Practices for the Data Platform

The Capability Maturity Model® Integration (CMMI) provides leading practices for project management.¹³ In our previous work, we have reported that effective project management requires an established governance structure and developing and implementing plans for the full scope of a project. This includes procedures for documenting deviations in cost and schedule performance, managing requirements, and identifying and analyzing risks.¹⁴

NIA had not fully implemented key project management leading practices for RWDP.¹⁵ For example, while NIA described high-level milestones and risks for the project and created a federal staffing plan, it did not establish a governance structure for achieving the project’s objectives and providing oversight for its planning and later development. Moreover, NIA did not develop a plan that included a detailed schedule, budget, and stakeholders needed for the project, record detailed requirements for the development of the core components, or create a risk management plan.¹⁶ Table 3 summarizes our assessment of the extent to which NIA implemented selected project management leading practices for RWDP.

¹³ISACA, *CMMI Model V3.0*.

¹⁴See, for example: GAO, *Information Technology: Better Management of Interdependencies between Programs Supporting 2020 Census Is Needed*, [GAO-16-623](#) (Washington, D.C.: Aug. 9, 2016) and *IT Modernization: HUD Needs to Improve Its Estimation and Oversight Practices for Single-Family Housing*, [GAO-21-459](#) (Washington, D.C.: Sept. 29, 2021).

¹⁵As noted earlier, we selected key leading practices from four practice areas related to project management identified by the ISACA Capability Maturity Model® Integration (CMMI®). The selected practice areas were (1) governance, (2) planning, (3) requirements development and management, and (4) risk management. Based on our professional judgement, we selected the simplest set of practices within these areas to address the full intent of each practice area.

¹⁶Core components were major functional pieces defined in the RWDP request for applications that the awardee of the cooperative agreement would have been responsible for establishing and developing. The core components included, among other things, administrative, research, data management, and integration functions.

Table 3: Extent to Which NIA Implemented Key Project Management Leading Practices for Managing the Development of the Real-World Data Platform (RWDP)

Practice area	Key leading practice	Analysis	Overall assessment
Governance	Ensure senior managers define the approach needed to accomplish objectives, including identifying information needs and using collected information to oversee process implementation.	NIA developed a request for applications that solicited applications for RWDP. The request for applications included plans for achieving the project objectives and milestones that defined what was important for developing the platform. However, NIA did not provide documentation to sufficiently define an approach to accomplishing the project’s objectives. Further, NIA did not provide evidence of identifying information needs and using collected information to provide oversight of implementation.	minimally implemented
Planning	Develop and keep updated a plan for the project that includes the knowledge, skills, schedule, budget, and stakeholders needed to perform the work.	NIA developed a federal staffing plan for RWDP that described the supply, demand, and gap analyses used in determining the staffing needs for the project. However, NIA’s plan for the project did not include key details about the schedule, budget, and stakeholders needed. For example, NIA officials stated that any project schedule would be developed by an eventual awardee of the cooperative agreement, guided by the required milestones in the request for applications. NIA officials also stated that NIA would have delegated the creation and implementation of plans for coordinating and integrating RWDP with large-scale health data organizations to the awardee.	partially implemented
Requirements development and management	Elicit stakeholder needs, develop a requirements management plan, and obtain commitment from project participants to implement a prioritized list of recorded requirements.	NIA developed a request for applications for RWDP that included some requirements for the project. However, NIA did not provide a requirements management plan or any documentation describing the elicitation of stakeholder needs, or commitment from project participants to implement requirements for RWDP.	minimally implemented
Risk management	Identify, record, analyze, monitor, and update risks, and communicate the status to stakeholders.	NIA developed a request for applications that had identified risks involved with perpetuating health disparities and biases in research, risks regarding data privacy for human participants of studies, and the overall risk of executing the platform. However, NIA’s strategy did not define RWDP’s risk management throughout the proposed duration of the project. Further, there was no documentation on recording, analyzing, monitoring, and updating risks for the project.	minimally implemented

Legend: ● – Fully implemented – NIA provided complete evidence that satisfies the entire criteria; ● - Substantially implemented – NIA provided evidence that satisfies a large portion of the criteria; ● - Partially implemented – NIA provided evidence that satisfies about half of the criteria; ● - Minimally implemented – NIA provided evidence that satisfies a small portion of the criteria; ○ – Not implemented – NIA provided no evidence that satisfies any of the criteria.

Source: GAO analysis of National Institute on Aging (NIA) information. | GAO-24-106886

NIA officials stated they were not required to implement these leading practices for cost estimating and project management, since such implementation would have been the awardee’s responsibilities. However, as the government agency with responsibility for how appropriated funds are spent, it will be important for NIA to consider implementing these practices in the future if a project of similar scope and scale as RWDP were to be developed. This would help ensure that the agency is well-positioned to substantially monitor, contribute to, and support a complex and costly effort with important implications for health research.

NIA Described Several Reasons for its Decision Not to Fund the Data Platform and Identified Lessons Learned

After deciding not to fund the RWDP project in April 2024, NIA provided context for its decision, as well as lessons learned to be applied to future efforts. Specifically, NIA officials stated that there were other large data initiatives that are under development at NIH and other federal agencies that could accommodate NIA's goals but also stated that it was too premature to identify any specific initiatives. Additionally, officials stated that there had been an increase in high-quality applications for Alzheimer's disease research grants and that only a limited number of those efforts could be funded.

In addition to the concerns expressed by Congress mentioned previously, and the details of our preliminary findings, which we shared with NIA prior to its decision not to fund RWDP, NIA officials said that the complexity of the project's solicitation offered lessons learned. These included:

- Projects of this size and scope involving real-world data require the involvement of staff with a broad range of expertise, especially when it comes to reviewing applications.
- Open collaboration with federal partners and other potential non-governmental organizations can facilitate better plans for project development.
- Representing data from diverse populations can be difficult, yet it is an essential responsibility for any real-world data project.
- Data vendors and aggregators play a critical role in the real-world data space with respect to costs, data ownership, and long-term viability of real-world data projects.
- Data privacy, protection, and consent are key considerations in any real-world data project.

Better access to data collected in real-world settings through projects such as RWDP could assist NIA in its goal of improving health outcomes for millions of Americans living with ADRD. Effectively managing such a complex and costly project would be a key factor in achieving this goal. While we are not making recommendations due to NIA's decision not to fund the data platform, our work demonstrates the importance of following and fully implementing the leading cost estimation and project management practices we described in this report.

Agency Comments and Our Evaluation

We requested comments on a draft of this report from the Department of Health and Human Services. HHS provided general comments, as further discussed below. These comments are reprinted in enclosure I. The department also provided technical comments which we incorporated as appropriate.

In its written comments, the department asserted that it is not subject to the cost estimating criteria that we used in our analysis of the RWDP because these best practices are applicable only to contracts and acquisitions. However, regardless of NIA's classification of RWDP as a research project funded by a cooperative agreement award, our *Cost Estimating and Assessment Guide*, and its associated best practices, are intended for use in any acquisition, program, project, or function that benefits from the use of cost estimating, such as the RWDP.


Further, HHS and NIH stated that the project management criteria we used in our report should not have been applied to RWDP because the cooperative agreement award had not been made. However, as the awarding institute for the RWDP cooperative agreement, NIA had general oversight, program planning, design, and risk requirements that needed to be addressed prior to the award of the cooperative agreement. An established governance structure and planning documents, as well as plans for requirements and risk management, would ensure that NIA management has the information it needs to make informed decisions for future development efforts.

Lastly, HHS claimed our application of criteria to the RWDP in this review would impact more than 100,000 HHS annual awards. However, as stated in our report, we specifically limited the scope of our findings to the RWDP cooperative agreement and at no point asserted that our findings applied more broadly to the universe of HHS's annual awards. As a result, we continue to believe that we appropriately applied the criteria used to review NIA's efforts to develop RWDP.

We are sending copies of this report to the appropriate congressional committees, the Director of NIA, the Director of NIH, the Secretary of HHS, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (214) 777-5719 or hinchmand@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 key contributions to this report included Tammi Kalugdan (Assistant Director), David Hong (Analyst-in-Charge), Lauri Barnes, Chris Businsky, Daniel Coletta, Andrew Erickson, Matthew Gray, Michael Lebowitz, Jason Lee, Jess Lionne, Asia Thomas, and Mary Weiland.

Sincerely,

A handwritten signature in black ink that reads "David B Hinchman". The signature is written in a cursive, flowing style with a long horizontal flourish at the end.

David B. Hinchman
Director, Information Technology and Cybersecurity

Enclosure

Enclosure 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

June 28, 2024

David B. Hinchman
Director, Information Technology and Cybersecurity
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Hinchman:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"NATIONAL INSTITUTE ON AGING: Leading Project Management Practices Are Important for Large-Scale Health Data Efforts"** (GAO-24-106886).

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 CORRESPONDENCE ENTITLED: "NATIONAL INSTITUTE ON AGING: LEADING PROJECT MANAGEMENT PRACTICES ARE IMPORTANT FOR LARGE-SCALE HEALTH DATA EFFORTS" (GAO-24-106886)

The Department of Health & Human Services (HHS) appreciates the review conducted by GAO and the opportunity to provide clarifications on this draft correspondence. HHS respectfully submits the following general comments, affirming concerns expressed to GAO throughout the engagement.

HHS and the National Institutes of Health (NIH) remain concerned that the criteria and analysis that GAO applied to this engagement pertaining to cost estimation are widely understood to apply to contracts/acquisitions; they are not broadly understood to apply to grants and cooperative agreements. Accordingly, these standards are not suitable criteria, as the National Institute on Aging's (NIA) proposed Alzheimer's and Related Dementias Real-World Data Platform (RFA-AG-24-009) would have resulted in a cooperative agreement award.

HHS/NIH remain concerned that the criteria and analysis that GAO applied to this engagement pertaining to project management are not suitable criteria, as an award had not yet been made. A federal awarding agency's management and oversight responsibilities for an award may only occur after an award is made and continue as the project commences. The management responsibilities of the award recipient and the federal awarding agency vary depending on the stage of the award lifecycle. Without an award, there are no award activities for NIH to oversee.

HHS/NIH are also concerned that GAO conflates what is required of the federal awarding agency in developing and administering grants and cooperative agreements and managing the associated federal budget, versus what is required of the applicant/recipient in developing their application and managing any subsequent award. The applicant/recipient is responsible for developing the proposed award budget, technical documentation as part of research strategy and approach, and other associated documentation for the cooperative agreement award, and for managing the funds made available under that award. The draft correspondence further does not acknowledge that the budget estimate included in any NIH Notice of Funding Opportunity (NOFO) is distinct from a cost estimate for an acquisition or other contract-funded project. Specifically, the NOFO estimate reflects only the **proposed** dollar amount to be spent *by the award recipient institution(s)*; it is not intended or appropriate to include NIH or other federal management and staffing costs in the proposed cooperative agreement award budget.

The principles at 2 CFR part 200/45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal/HHS Award (UAR), apply to grant and cooperative agreement awards. These principles — including cost principles — guide the federal awarding agency and the applicant/recipient in determining whether costs under the award are allowable, allocable, reasonable, and necessary. These principles typically guide determinations related to cost when conducting audits or similar oversight activities, including pre-award review activities, which NIH/NIA performed. The draft correspondence omits the significant pre-award work NIH/NIA performed, consistent with expectations as established in the UAR and other federal regulations, i.e., expectations that provide suitable context for evaluation.

The feasibility of assessing each of the more than 100,000 HHS annual awards against the GAO best practices guidance — and establishing a new expectation that applicants and recipients build their applications against this GAO guidance — would result in significant administrative burden for all.

While NIA ultimately did not make an award in response to RFA-AG-24-009, GAO’s assertion that their “work demonstrates the importance of following and fully implementing the leading cost estimation and project management practices” sets broader, federal-wide implications and may impact trillions of dollars of federal financial assistance. The potential effects of such a shift on the grants community, primarily applicants and recipients, run counter to the priority of lowering barriers to access to grants and enhancing equity.

June 28, 2024

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Director, Information Technology and Cybersecurity
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

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Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

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HHS and the National Institutes of Health (NIH) remain concerned that the criteria and analysis that GAO applied to this engagement pertaining to cost estimation are widely understood to apply to contracts/acquisitions; they are not broadly understood to apply to grants and cooperative agreements. Accordingly, these standards are not suitable criteria, as the National Institute on Aging's (NIA) proposed Alzheimer's and Related Dementias Real-World Data Platform (RFA-AG-24-009) would have resulted in a cooperative agreement award.

HHS/NIH remain concerned that the criteria and analysis that GAO applied to this engagement pertaining to project management are not suitable criteria, as an award had not yet been made. A federal awarding agency's management and oversight responsibilities for an award may only occur after an award is made and continue as the project commences. The management responsibilities of the award recipient and the federal awarding agency vary depending on the stage of the award lifecycle. Without an award, there are no award activities for NIH to oversee.

HHS/NIH are also concerned that GAO conflates what is required of the federal awarding agency in developing and administering grants and cooperative agreements and managing the associated federal budget, versus what is required of the applicant/recipient in developing their application and managing any subsequent award. The applicant/recipient is responsible for developing the proposed award budget, technical documentation as part of research strategy and approach, and other associated documentation for the cooperative agreement award, and for managing the funds made available under that award. The draft correspondence further does not acknowledge that the budget estimate included in any NIH Notice of Funding Opportunity (NOFO) is distinct from a cost estimate for an acquisition or other contract-funded project. Specifically, the NOFO estimate reflects only the proposed dollar amount to be spent by the award recipient institution(s); it is not intended or appropriate to include NIH or other federal management and staffing costs in the proposed cooperative agreement award budget.

The principles at 2 CFR part 200/45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal/HHS Award (UAR), apply to grant and cooperative agreement awards. These principles — including cost principles — guide the federal awarding agency and the applicant/recipient in determining whether costs under the award are allowable, allocable, reasonable, and necessary. These principles typically guide determinations related to cost when conducting audits or similar oversight activities, including pre-award review activities, which NIH/NIA performed. The draft correspondence omits the significant pre-award work NIH/NIA performed, consistent with expectations as established in the UAR and other federal regulations, i.e., expectations that provide suitable context for evaluation.

The feasibility of assessing each of the more than 100,000 HHS annual awards against the GAO best practices guidance — and establishing a new expectation that applicants and recipients build their applications against this GAO guidance — would result in significant administrative burden for all.

While NIA ultimately did not make an award in response to RFA-AG-24-009, GAO's assertion that their "work demonstrates the importance of following and fully implementing the leading cost estimation and project management practices" sets broader, federal-wide implications and may impact trillions of dollars of federal financial assistance. The potential effects of such a shift on the grants community, primarily applicants and recipients, run counter to the priority of lowering barriers to access to grants and enhancing equity.