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Decision

Matter of: Navitas Clinical Research, Inc.

File: B-422142.3; B-422142.4

Date: July 10, 2024

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DIGEST

1. Protest that the awardee has an unequal access to information organizational conflict of interest arising from a meeting between the agency, the protester, and the awardee with respect to the protester's performance of predecessor requirements for the agency and the awardee's performance on an unrelated contract is denied because the protester fails to establish that the meeting resulted in the awardee gaining access to any of the protester's proprietary information.
2. Protest challenging the agency's evaluation of the protester's proposal under the technical and past performance factors is denied where the record shows that the agency's evaluation was reasonable and consistent with the terms of the solicitation and procurement laws and regulations.
3. Protest that the agency conducted misleading discussions is denied where the discussions reasonably led the protester to the areas of its proposal that were the basis for the agency's evaluated concerns.

DECISION

Navitas Clinical Research, Inc. (Navitas), a small business located in Rockville, Maryland, protests the award of an indefinite-delivery, indefinite-quantity (IDIQ) contract and issuance of an initial task order to Digital Infuzion, Inc. (Digital), of Rockville,

Maryland, under request for proposals (RFP) No. 75N95023R00013, issued by the Department of Health and Human Services (HHS), National Institutes of Health (NIH), National Institute of Aging (NIA), for clinical research support services. Navitas argues that Digital has an unmitigated unequal access to information organizational conflict of interest (OCI), alleges the agency's evaluation of its proposal was unreasonable, and contends that the agency engaged in misleading discussions.

We deny the protest.

BACKGROUND

NIA leads the federal government's research efforts related to the health and well-being of older people and oversees a current and evolving clinical research portfolio. Contracting Officer Statement (COS) at 1. The mission of NIA's Office of Clinical Research (OCR) is to manage, support administrative operations, and to ensure that NIA is strategically and proactively planning, implementing, and monitoring best practices to comply with federal clinical research regulatory and policy requirements. *Id.* As part of that effort, NIA sought to acquire the services of a contractor to assist NIA with producing centralized procedures for tracking clinical research, regulatory compliance, and quality assurance/quality control activities.¹ *Id.*

The procurement at issue--referred to as NIA Clinical Research Support Services (CRSS)--sought proposals to provide a broad range of centralized and integrated administrative, regulatory, logistic, and statistical support for managing NIA's current and evolving clinical research portfolio. AR, Exh 2b, RFP at 4.² The contractor will provide support services to include project management and implementation, regulatory expertise, quality assurance/quality control, promoting participant recruitment, statistical consultation, developing tools, templates, and trainings, and managing participant safety, data integrity, and trial progress. *Id.*

NIA issued the solicitation for the CRSS contract on February 16, 2023, on an unrestricted basis, pursuant to the procedures of Federal Acquisition Regulation (FAR) part 15 and section 16.504. AR, Exh. 2b, RFP at 4. The RFP was amended once to include revisions to the technical and past performance evaluation factors and to address questions from prospective offerors regarding the solicitation. AR, Exh. 2e, RFP amend. 1. As amended, the solicitation contemplated the award of a single IDIQ contract under which NIA would acquire services and deliverables by issuing cost-reimbursement task orders. AR, Exh. 2b, RFP at 56. The RFP contemplated award of

¹ The NIA divisions involved in this effort are the divisions of: (1) aging biology; (2) behavioral and social research; (3) geriatrics and clinical gerontology; and (4) neuroscience. Agency Report (AR), Exh. 2c, RFP attach. 3, IDIQ Statement of Work (SOW) at 1.

² Unless otherwise noted, citations to the RFP and its associated attachments, as well as other agency report exhibits, are to the Adobe PDF pagination.

an IDIQ contract with a 5-year period of performance and a maximum ordering value in excess of \$49 million. *Id.*

The scope of work for the IDIQ contract included seven distinct work areas connected with specific tasks: (1) project management; (2) regulatory oversight and support, including support and oversight of data and safety monitoring boards (DSMBs)³; (3) analytics monitoring including data entered into NIA's clinical research operations and management system (CROMS); (4) recruitment and retention; (5) clinical research operations support and quality assurance; (6) statistical and methodological consultation; and (7) training of NIA staff in clinical research procedures. AR, Exh. 2c, RFP attach. 3, IDIQ SOW at 8.

The RFP also contemplated issuance of an initial task order--referred to here as the OCR Project Management, DSMB and CROMS-related task order--concurrently with award of the IDIQ contract. AR, Exh. 2c, RFP attach. 6, Additional Business Proposal Instructions at 20. The initial task order will be issued on a cost-plus-fixed-fee basis for a base year with four 1-year option periods. AR, Exh. 2e, RFP amend. 1, attach. 6, Additional Business Proposal Instructions at 18. This initial task order will provide administrative and project management as well as technical support activities to OCR and other NIA divisions. AR, Exh. 2c, RFP attach. 7, Task Order SOW at 23. Under this task order, the contractor will provide support services associated with work areas Nos. 1-6 as described in the task order SOW. AR, Exh. 2c, RFP attach. 7, Task Order SOW at 23-27.

The solicitation established that award would be made using a best-value tradeoff based on three evaluation factors--technical, cost, and past performance. AR, Exh. 2b, RFP at 85. Under the technical factor, proposals were to be assigned up to 100 points, based on the evaluation of three subfactors: (1) technical approach and management (40 points); (2) staffing and personnel qualifications (35 points); and (3) organizational experience (25 points). *Id.* at 85-86. For purposes of award, the non-cost factors, when combined, were significantly more important than cost. *Id.* The RFP advised offerors that award might be made to other than the lowest-priced offeror or other than the highest technically rated offeror. *Id.* at 61.

³ NIH policy requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants. See "NIH Policy for Data and Safety Monitoring," NIH (June 10, 1998), available at <https://grants.nih.gov/grants/guide/notice-files/not98-084.html> (last visited July 2, 2024).

A DSMB is charged with monitoring the safety of participants and the quality of the data, as well as the appropriate termination of studies either when significant benefits or risks have been uncovered or when it appears that the clinical trial cannot be concluded successfully. "Guidelines for Establishing and Operating a Data and Safety Monitoring Board," HHS (Oct. 1, 2018), available at <https://www.hhs.gov/guidance/document/guidelines-establishing-and-operating-data-and-safety-monitoring-board> (last visited July 2, 2024).

The RFP instructed offerors to submit their proposals in two volumes--a technical proposal and a business proposal. AR, Exh. 2b, RFP at 58. In their technical proposals, offerors were to include: technical discussions that respond to the SOW requirements; a description of the experience and qualifications of personnel assigned to work on the program; and the qualifications of the offeror, including its organizational experience. *Id.* at 69-72. Additionally, offerors were to address the requirements of the task order SOW. *Id.* at 23-27. In their business proposals, offerors were to include cost or price information for the task order and to include information regarding their past performance references. AR, Exh. 2e, RFP amend. 1, attach. 6, Additional Business Proposal Instructions at 18.

The RFP provided for the evaluation of proposals using a tiered evaluation process. AR, Exh. 2b, RFP at 60; COS at 3. The technical portion of each proposal was subject to peer review pursuant to NIH's guidance.⁴ COS at 3-4; Memorandum of Law (MOL) at 2-3. The peer review would be conducted by an independent special emphasis panel (SEP) by evaluating the scientific and technical portion of proposals under the technical factor and subfactors, assigning numerical scores for each subfactor, and preparing technical evaluation summaries identifying the strengths and weaknesses of each proposal. COS at 3-4.

If an offeror's proposal was evaluated as technically acceptable, the agency then would assess the offeror's past performance for recency, relevancy, and quality. AR, Exh. 2e, RFP amend. 1 at 3. Each offeror could submit five past performance references completed during the past five years and all contracts currently being performed that are similar in nature to the solicitation's SOW. AR, Exh. 2b, RFP at 62. The RFP also stated that the agency would assess the relative performance risks associated with each offeror's record of performance as it relates to all acquisition requirements. *Id.* at 87. Performance risks were stated to be those associated with an offeror's likelihood of success in performing the solicited acquisition requirements as indicated by the offeror's record of past performance. *Id.*

The next step in the evaluation process was a review by NIA program officials of the SEP's evaluation findings and recommendations and to develop questions for those offerors recommended for further consideration. COS at 4. More specifically, program officials would review the offerors' proposals and the SEP technical evaluation summaries, including the identified strengths and weaknesses of each offeror. *Id.*

⁴ NIH is required by statute to use a scientific peer review panel to conduct the technical review of proposals for research and development contracts. COS at 3 (*citing*, 42 U.S.C. subpart 289a, Peer Review Requirements; 42 C.F.R. part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects). In addition, the agency reports that the peer reviewers were selected based on their expertise in the required scientific or technical disciplines. COS at 4 (*citing*, NIH Policy Manual chapter 6315-1(B)).

As to the offerors' business proposals, the RFP provided that they should contain sufficient cost/price information to allow the agency to perform an analysis of the proposed cost/price of the work. AR, Exh. 2b, RFP at 73. Offerors' business proposals would be evaluated for reasonableness and realism, and the results of the cost realism analysis would be considered in the best-value tradeoff decision. *Id.* at 85.

NIA received proposals from seven offerors, including Digital and Navitas, by the extended closing date of March 27. COS at 3. The SEP evaluated the initial proposals, and found six were technically acceptable, including those submitted by Digital and Navitas. Digital received a total technical score of 88.67 out of 100 possible points; Navitas received a total technical score of 83.67 points, which was 8.66 points below the highest rated proposal. *Id.* at 3-4; AR, Exh. 4j, Source Selection Determination Mem. at 3-4. Digital's evaluated total cost for the initial task order was \$25,475,816.63. COS at 4. Navitas's evaluated total cost was \$29,125,761, which was 7 percent higher than the independent government cost estimate (IGCE) of \$27,242,579.64. AR, Exh. 4f, Review of Business Proposals at 3.

The agency initially established a competitive range comprised of proposals submitted by Digital and another competing offeror (referred to here as Offeror A). COS at 5. Navitas was informed that its proposal had been excluded from the competitive range, and in response, Navitas filed a protest with our Office on October 17 and a supplemental protest on October 23. The agency notified our Office of its intent to take corrective action by including the protester's proposal in the competitive range and conducting discussions with the protester; consequently, our Office dismissed the protests as academic. *See Navitas Clinical Research, Inc.*, B-422142; B-422142.2, Nov. 2, 2023 (unpublished decision). On December 6, the agency included Navitas's proposal in the competitive range. AR, Exh. 4c, Amended Competitive Range Determination Mem. at 3.

The agency conducted discussions by issuing negotiation letters and requesting revised proposals from the three competitive range offerors.⁵ *See, e.g.*, AR, Exh. 3e, Navitas First Req. for Revisions at 1-9. After evaluating revised proposals, the agency issued a second round of negotiation letters and requested second revised proposals. AR, Exh. 3o, Navitas Second Req. for Revisions at 1-10. Following two rounds of discussions, the agency requested final proposal revisions. *See, e.g.*, AR, Exh. 3x, Navitas Final Proposal Revisions Letter. Navitas timely submitted its final proposal revisions on January 10, 2024. AR, Exh. 3z, Navitas Final Technical Submission; Exh. 3aa, Navitas Final Business Submission.

The NIA program officials evaluated the offerors' final proposal revisions and prepared an evaluation report that summarized the evaluation findings and rationale under each evaluation factor. AR, Exh. 4k, Final Proposal Revisions Eval. Report. For Navitas, the evaluators identified various strengths and discussed how those strengths benefited the

⁵ The proposal submitted by Offeror A is not relevant to this protest and, therefore, is not further discussed.

government. The evaluators also identified various weaknesses in the protester's final proposal revisions and discussed how those weaknesses posed a performance risk. See, *id.* at 15-22. Navitas's final evaluated cost for the initial task order was \$25,211,183, which was 7.46 percent lower than the IGCE. AR, Exh. 4j, Source Selection Determination Mem. at 14. Digital's final evaluated cost for the initial task order was \$25,319,682. AR, Exh. 5b, Award Notification at 1.

The source selection authority (SSA) reviewed and concurred with the program officials' evaluation of the offerors' final proposal revisions and prepared a decision memorandum to document her qualitative assessment of the technical differences between the offerors. AR, Exh. 4j, Source Selection Determination Mem. at 16-27. In making the selection decision, the SSA compared the relative strengths, weaknesses, and risks of each proposal and performed a tradeoff between the technical merits and cost/price. The SSA determined that Digital's proposal represented the best value to the government and selected Digital's proposal for award. COS at 6.

After receiving notification of the award decision and a debriefing, Navitas filed an initial and supplemental protest with our Office.

DISCUSSION

Navitas's initial and supplemental protests raise multiple protest grounds. The protester contends that Digital was ineligible for award because of an unequal access to information OCI and challenges various aspects of NIA's evaluation of its proposal under the technical and past performance evaluation factors.⁶ The protester also alleges that the agency conducted misleading discussions.

While we do not herein specifically discuss each and every argument or variation of the arguments raised, we have considered all of Navitas's allegations and, as discussed below, through several representative examples of the protester's arguments, the agency's and the intervenor's responses, and our conclusions, we find no basis on which to sustain the protest.

Unequal Access to Information OCI

Navitas contends that Digital has an unmitigable unequal access to information OCI and therefore was ineligible for award. Protest at 8-10; Protester's Comments at 1-5. In

⁶ In its supplemental protest, Navitas challenged the agency's cost realism analysis of Digital's proposal, arguing that Digital did not include honoraria costs in its initial task order proposal. Supp. Protest at 46-47. In response to the agency's request for dismissal of this basis of protest, Navitas withdrew this allegation. Protester's Resp. to Req. for Dismissal at 11.

advancing this argument, the protester focuses on a March 31, 2023, Zoom⁷ meeting, attended by Navitas personnel, NIA personnel, and Digital's program director. *Id.* Relevant here, Digital was the incumbent contractor for NIA's CROMS system development contract, and Navitas was the incumbent contractor for NIA's Clinical Trials Operations Support Center (CTOSC) contract. Req. for Dismissal Exh. 3, Decl. of OCR Director ¶¶ 3, 7 at 1-2. Under its CTOSC contract, Navitas performed regulatory support and oversight tasks for NIA's division of behavioral and social research (BSR) concerning DSMBs, which is one of the divisions that will be supported under this protested procurement. Req. for Dismissal at 3; *see also*, Req. for Dismissal Exh. 3, Decl. of OCR Director ¶ 7 at 2.

The protester claims that proprietary information concerning its practices and strategies under its CTOSC contract, as well as information as to the number of DSMBs it manages and for which NIA divisions, were discussed, and thereby revealed the protester's nonpublic, competitively useful information to Digital.⁸ *See* Protest at 9-10 *citing*, Exh. D, Decl. of Navitas's Assoc. Vice President ¶¶ 6-9 at 1; *see also*, Protester's Resp. to Req. for Dismissal at 3.

The agency and intervenor strenuously object to the protester's characterization that any information disclosed during the call was proprietary in nature. The agency and intervenor argue that the purpose of the call was to discuss Navitas's experience implementing the agency's published DSMB standard operating procedures (SOPs) in order to build a DSMB/Safety Officer (DSMB/SO) module in the existing CROMS system. *See, e.g.*, Req. for Dismissal, Exh. 3, Decl. of OCR Director ¶ 4 at 1; *see also* Intervenor's Resp. to Req. for Dismissal, Exh. A, Decl. of Digital's Program Manager, ¶ 13 at 3 ("The purpose of the Call was to understand what metrics relevant to DSMBs that should be tracked in the new module in NIA CROMS."). Specifically, the agency sought clarification regarding: (1) how many DSMBs Navitas was managing and for what divisions; (2) confirmation of the steps and processes delineated in the published documents; and (3) information about any challenges Navitas encountered in carrying out the published SOPs. Req. for Dismissal, Exh. 3, Decl. of OCR Director, at ¶ 7 at 2; *see also* COS at 7 ("All steps discussed are part of the NIH/NIA DSMB processes described on publicly available websites; [t]he conversation was limited to one NIA division, which also has a dedicated public website describing its DSMB process [].

⁷ Zoom is a software platform used for video communications, messaging, voice calls, conference rooms for video meetings, virtual events, and contact centers.

⁸ In response to the protester's initial allegations, NIA, in its request for dismissal, refuted the protester's claim that Digital gained unequal access to source selection information during the Zoom meeting. Req. for Dismissal at 2-5; *see also*, Intervenor's Resp. to Req. for Dismissal Exh. A, Decl. of Digital's Program Director ¶ 23 at 5. In response, Navitas subsequently clarified that any reference to source selection information as an additional basis for its OCI protest "was an inadvertent result of protester's attempts to demonstrate [Digital's] access to its proprietary information prior to proposal revisions." Protester's Resp. to Req. for Dismissal at 3 n.1.

Navitas did not disclose any proprietary systems or processes but instead talked about the use of emails, Zoom, and SharePoint⁹ used to manage the steps discussed.”); *id.*, COS Table 1, NIA Summary of Public and Proprietary Information Related to Decl. of OCR Director (providing a mapping of topics discussed and links to available supporting information on publicly available websites); Intervenor’s Resp. to Req. for Dismissal, Exh. A, Decl. of Digital’s Program Manager, ¶¶ 21 at 4-5 (“The Navitas personnel on the Call discussed generic, high-level functions concerning the DSMB oversight process and NIA’s publicly available SOPs to help the NIA and Digital [] determine what metrics should be used in a new NIA CROMS module for tracking and managing the DSMBs overseeing NIA studies.”).

The FAR instructs agencies to identify potential OCIs as early as possible in the procurement process, and to avoid, neutralize, or mitigate potential significant conflicts of interest so as to prevent an unfair competitive advantage. FAR 9.504(a), 9.505. Subpart 9.5 of the FAR, and decisions of our Office, broadly identify three categories of OCIs: biased ground rules, unequal access to information, and impaired objectivity.

As relevant here, an unequal access to information OCI arises where a firm has access to nonpublic information as part of its performance of a government contract, and where that information may provide the firm an unfair competitive advantage in a later competition for a government contract. FAR 9.505(b); *Cyberdata Techs., Inc.*, B-411070 *et al.*, May 1, 2015, 2015 CPD ¶ 150 at 6. As the FAR makes clear, the concern regarding this category of OCIs is that a firm may gain a competitive advantage based on its possession of “[p]roprietary information that was obtained from a Government official without proper authorization” or “[s]ource selection information . . . that is relevant to the contract but is not available to all competitors, and such information would assist that contractor in obtaining the contract.” FAR 9.505(b); see *ITT Corp.--Elec. Sys.*, B-402808, Aug. 6, 2010, 2010 CPD ¶ 178 at 5.

Furthermore, proprietary information for purposes of OCIs generally means bid or proposal information or information marked as proprietary. FAR 3.104-1. Bid or proposal information refers to information submitted to a federal agency as part of, or in connection with, a bid or proposal submitted for a federal agency procurement. Such information can include cost or pricing data and proprietary information about manufacturing processes, operations, or techniques marked by the contractor in accordance with applicable law or regulation. *Id.*

The record indicates that NIA requested a meeting with Navitas to discuss the processes utilized by Navitas to support NIA’s DSMB needs. Req. for Dismissal Exh. 3, Decl. of OCR Director ¶¶ 4, 7 at 1-2. As the meeting organizer, that planned, scheduled, and monitored the meeting from its company’s Zoom account, Navitas was informed of the agency attendees, and had received email confirmation that Digital’s program director had accepted the invitation to the Zoom meeting. Req. for Dismissal

⁹ SharePoint is a browser-based application that allows for storage, retrieval, searching, archiving, tracking, management, and reporting on electronic documents and records.

Exh. 3, Decl. of OCR Director ¶¶ 8-10 at 2; Intervenor's Resp. to Req. for Dismissal Exh. A, Decl. of Digital's Program Manager ¶ 13 at 3. During the meeting, all participants' names and information were clearly displayed in the standard Zoom format and Digital's program director also introduced himself and spoke during the meeting. Intervenor's Resp. to Req. for Dismissal Exh. A, Decl. of Digital's Program Manager ¶¶ 10-11 at 2.

The agency and the intervenor both deny Navitas's claim that the meeting involved discussion of the protester's nonpublic proprietary information. Both parties insist that the discussions were based on information that is publicly available on the NIA clinical research study investigator's toolbox available at <https://www.nia.nih.gov/research/clinical-research-study-investigators-toolbox> or were otherwise general, high-level information that did not address any of Navitas's proprietary methods. See generally, Req. for Dismissal at 3-5; Req. for Dismissal Exh. 3, Decl. of OCR Director at 1-3; see also, Intervenor's Resp. to Req. for Dismissal at 2-5; Intervenor's Resp. to Req. for Dismissal Exh. A., Decl. of Digital's Program Director at 1-5.

In this regard, the agency reports that the meeting was held to discuss the development of a new CROMS DSMB module that will standardize the management of NIA's DSMBs, and the meeting topics included: background information for development of the CROMS DSMB module; discussion of the number of active clinical trials with DSMBs supported by Navitas; and discussion of Navitas' support of NIA's DSMBs.¹⁰ COS at 7 citing, Req. for Dismissal Exh. 3, Decl. of OCR Director ¶ 11 at 2-3; see also, COS Table 1, NIA Summary of Public and Proprietary Information Topics at 1-2.

Despite Navitas's assertions that Digital gained unequal access to proprietary information during the meeting, we see no evidence that this was the case. As noted, the FAR defines the type of information generally considered proprietary information for purposes of conflicts of interest. See FAR 3.104-1. The record indicates that Navitas has not been entirely clear, nor provided specific details, regarding the practices and strategies under its CTOSC contract, see Protest Exh. D, Decl. of Navitas Assoc. Vice President ¶ 1 at 1, that would fall within the FAR definition of proprietary information or that otherwise would have provided a competitive advantage to Digital.¹¹

¹⁰ The intervenor points out that under Navitas's existing contract with NIA, Navitas performs the executive secretary function for DSMBs in two of the four NIA divisions of NIA's extramural research program. Intervenor's Resp. to Req. for Dismissal Exh. A, Decl. of Digital's Program Manager ¶ 15 at 3. According to the intervenor, the executive secretary function is an industry-standard function that applies to all operational DSMBs and that there is nothing unique or proprietary about the responsibilities and processes related to the role of executive secretary. *Id.*

¹¹ It also bears noting that the meeting occurred after offerors had submitted their initial proposals, and Digital's initial proposal was evaluated as technically superior to Navitas's initial proposal. See, e.g., AR, Exh. 4c, Amended Competitive Range

(continued...)

Moreover, nothing in the record indicates that Navitas made any effort to protect information that it claims was proprietary despite being fully aware that another contractor--Digital--was participating in the meeting. If Navitas believed proprietary information would be discussed, the protester should have notified the agency and asked that the information be protected. Under the FAR, information that is voluntarily disclosed without limitations on its use is not considered proprietary and the FAR provisions concerning OCIs will not apply to such information. Intervenor's Comments at 7 (*citing*, FAR 9.505-4(a)). We agree.

Nonetheless, Navitas claims that information regarding its performance under its NIA CTOSC contract, which included predecessor support for one of the four agency divisions to be covered under this protested procurement, was discussed during the meeting and identified this information as "deeply proprietary." Protester's Comments at 4. However, Navitas does not explain why it failed to notify the agency or tell any participants at the meeting that this information was proprietary; instead, the protester simply states that it "would never have shared [this information] with a known competitor, let alone one that actually bid on the same [solicitation as] it did." *Id.* We have stated previously that a protester must identify "hard facts" that indicate the existence or potential existence of a conflict; mere inference or suspicion of an actual or potential conflict is not enough. See *LOGZONE, Inc.*, B-416029, B-416029.2, May 21, 2018, 2018 CPD ¶ 190 at 4; *DRS Tech. Servs., Inc.*, B-411573.2, B-411573.3, Nov. 9, 2015, 2015 CPD ¶ 363 at 11-12. Since Navitas has failed to demonstrate that Digital had unequal access to proprietary information, we deny this protest ground.

Technical Evaluation

Navitas challenges multiple aspects of the agency's evaluation of its proposal under the technical evaluation subfactors. Specifically, the protester alleges that its proposal was unfairly assigned 12 weaknesses because the agency ignored responsive information in its proposal. Supp. Protest at 21-32. Additionally, Navitas identified 10 weaknesses it alleges resulted from the agency applying unstated evaluation criterion. *Id.* at 32-42. Below, we discuss a few representative arguments.

In reviewing a protest challenging an agency's evaluation, our Office will not reevaluate proposals, nor substitute our judgment for that of the agency, as the evaluation of proposals is a matter within the agency's discretion. Rather, we will review the record to determine whether the agency's evaluation was reasonable and consistent with the stated evaluation criteria and with applicable procurement statutes and regulations. *AECOM Mgmt. Servs., Inc.*, B-417639.2, B-417639.3, Sept. 16, 2019, 2019 CPD ¶ 322 at 9; *Computer World Servs. Corp.*, B-410513, B-410513.2, Dec. 31, 2014, 2015 CPD ¶ 21 at 6.

Determination, at 1-2 (explaining that Navitas's initial proposal was rated third behind Digital and Offeror A).

While agencies are not permitted to use unstated evaluation factors in evaluating proposals, an agency properly may take into account specific matters that are logically encompassed by, or related to, the stated evaluation criteria, even when they are not expressly identified as evaluation criteria. *Perspecta Enter. Sols., LLC*, B-416377.6, B-416377.7, April 2, 2020, 2020 CPD ¶ 136 at 6. A protester's disagreement with the agency's judgment, without more, is insufficient to establish that the agency acted unreasonably. *Vertex Aerospace, LLC*, B-417065, B-417065.2, Feb. 5, 2019, 2019 CPD ¶ 75 at 8.

By way of example, Navitas disagrees with the agency's assessment of a weakness based on the limited information provided in its proposal regarding how Navitas will partner with its subcontractor under the contract and in addressing new task orders. Supp. Protest at 22-23; Protester's Comments at 8-9.

Under the technical approach and management subfactor, the RFP required offerors to describe its procedures for competition, selection, and oversight of any proposed subcontractors/consultants and to clearly define how any proposed arrangements would meet program needs and describe how subcontractor/consultant arrangements will be structured, organized, managed, and monitored. AR, Exh. 2e, RFP amend. 1, attach. 5, Additional Technical Proposal Instructions at 15.

The record shows that after evaluating Navitas's final proposal revisions, NIA program officials noted "there remains limited information on what the subcontractor, [[DELETED]], will do with the contract and the details of how they will partner with [Navitas], which becomes a substantial weakness identified for [work area 1]." AR, Exh. 4k, Final Proposal Revisions Eval. Report at 16. The evaluators further noted that "there is limited information on how [Navitas] will work with [DELETED] to address new [task orders] and determine work distribution between the two companies." *Id.*

The protester principally points to the section of its proposal titled "Working with [DELETED]" as support for its proposition that it adequately addressed these requirements. AR, Exh. 3z, Navitas Final Technical Submission at 61. However, we agree with the agency that other than addressing prior collaboration between the parties and initial contract transition, this section provides only high-level generalities regarding these required management issues. Specifically, the proposal merely states that:

Post the kickoff meeting, communication between [Navitas] and [DELETED] will continue on a weekly basis to ensure continuous and on-time efficient support for the project. Throughout the life of the contract, [Navitas] will receive updates from [DELETED] and will provide [DELETED] with updates on any contract changes. Further, [Navitas] will proactively work with [DELETED] to anticipate and manage any challenges that may arise during the project. . . . One way that [Navitas] will proactively mitigate these risks is to ensure from the start that [DELETED] has sufficient staffing for the contract throughout all phases of the project and create a succession and transition plan in case a transition

is needed during the scope of the contract. Consistent and clear lines of authority and communication among the team members will also be utilized as an effective approach for work on NIA CRSS.

Id.

Based on this record, we find no basis to question the agency's conclusions. Navitas's response did not provide clear details related to meeting program needs or the structure, organization, management or monitoring of its subcontractor by Navitas which amounted to a weakness. Nor has Navitas effectively rebutted the agency's finding that the proposal lacked detail related to the specific management requirements of the solicitation; while it may disagree as to the level of detail needed by the agency, the protester's disagreement, without more, does not form a sufficient basis to demonstrate that the assignment of a weakness in this regard was unreasonable. *Leidos Innovations Corp.*, B-415514 *et al.*, Jan. 18, 2018, 2018 CPD ¶ 88 at 16. In this regard, it is an offeror's responsibility to submit a well-written proposal, with adequately detailed information which clearly demonstrates compliance with the solicitation requirements and allows a meaningful review by the procuring agency. *A-P-T Research, Inc.*, B-419459, March 12, 2021, 2021 CPD ¶ 151 at 8. An offeror that does not affirmatively demonstrate the merits of its proposal risks rejection of its proposal or risks that its proposal will be evaluated unfavorably where it fails to do so. *Johnson Controls, Inc.*, B-407337, Nov. 20, 2012, 2012 CPD ¶ 323 at 4.

By way of another example, Navitas disagrees with the agency's assessment of a weakness based on concerns that its proposal did not demonstrate sufficient knowledge of proposed staff with respect to NIA's clinical trial enterprise or knowledge of clinical research oversight sufficient to develop SOPs. Supp. Protest at 30; Protester's Comments at 17-19. Relevant here, SOW work area 5, titled "clinical research operations support and quality assurance," requires the contractor to ensure that the data resulting from NIA studies are of the highest quality and are considered valid and credible within the scientific and clinical community. AR, Exh. 2c, RFP attach. 3, IDIQ SOW at 11. To accomplish this objective, the contractor will provide assistance and guidance from experts in clinical research quality assurance. *Id.* Mandatory tasks shall include: (1) monitoring for changes in regulations, guidelines, and clinical trials enterprise standards to ensure integrity and data quality for NIA-funded clinical research studies; (2) assisting with the development and maintenance of NIA clinical research SOPs and policies and ensuring that these are updated to meet all applicable requirements, including institutional, regulatory, and policy requirements; (3) assisting in the review of study documentation in CROMS, as needed, for quality, internal consistency and compliance with Good Clinical Practice and other Federal, State, and local laws/regulations including Food and Drug Administration (FDA), HHS, HHS-Office of Human Research Protections (OHRP), NIH, and NIA; and (4) reviewing and processing relevant regulatory documents to ensure compliance with all relevant NIA, NIH, HHS, and FDA regulations. *Id.* at 11-12.

The evaluators assessed a weakness for the staff proposed by Navitas for work area 5 because the staff's experience was either unclear or did not align with NIA's needs. Specifically, the agency found that the staff "did not demonstrate knowledge of NIA's clinical trial enterprise nor knowledge of clinical research oversight to develop a list of SOPs that NIA should have to define their oversight of clinical research and does not mention compliance with applicable regulations (OHRP, FDA) or NIH policies." AR, Exh. 4k, Final Proposal Eval. Report at 19. While the protester points to the general description of its proposed staff's experience in the pharmaceuticals and biologic industries, including the preparation of regulatory materials, see, e.g., AR, Exh. 3z, Navitas Final Revised Technical Proposal, at 89-90, 92, 101-102, these sections do not specifically address many of the tasks enumerated above, including with respect to the areas found lacking by the agency.¹²

In sum, we have reviewed the record and reject Navitas's arguments that the agency ignored information in its proposal concerning the qualification of its proposed personnel. We therefore find the agency's assessment of this weakness here to be reasonable.

Misleading Discussions

Navitas alleges that the agency conducted misleading discussions because the agency did not clearly identify the nature of its actual concerns in two areas of its proposal. Specifically, the protester claims the agency conducted misleading discussions concerning its data management system. Supp. Protest at 19-20; Protester's Comments at 5-6. Next, the protester claims it was misled concerning the agency's concerns with the protester's approach to data mining. Supp. Protest at 20-21; Protester's Comments at 6-8. In response, the agency argues that its discussions were not misleading as the discussion questions adequately led the protester into the areas of the agency's identified concerns.

¹² To the extent that the protester points to other sections of its proposal, for example its organizational experience and relevant technical experience section, to bolster the lack of supporting detail in the required staffing plan and personnel qualifications section of its proposal, such efforts fail to provide a basis on which to sustain the protest. As addressed above, it is an offeror's responsibility to submit a well-written proposal, with adequately detailed information which clearly demonstrates compliance with the solicitation requirements and allows a meaningful review by the procuring agency. *A-P-T Research, Inc., supra*. The RFP directed that offerors were to demonstrate the education and experience of personnel in the staffing plan and personnel qualifications portion of their proposals. AR, Exh. 2b, RFP at 86. The agency was not required to make inferences and search for information not presented in the manner required by the solicitation. See, e.g., *CACI, Inc.--Fed.*, B-420729.2, Mar. 1, 2023, 2023 CPD ¶ 51 at 11 (explaining that "an agency generally is not required to search other sections of an offeror's proposal for information to meet requirements related to a different section").

It is a fundamental principle of negotiated procurements that discussions, when conducted, must be meaningful; that is, discussions must identify proposal deficiencies, and significant weaknesses in an offeror's proposal that reasonably could be addressed so as to materially enhance the offeror's potential for receiving award. See *Acuity-Exemplar, JV*, B-418428, Apr. 7, 2020, 2020 CPD ¶ 138 at 64. An agency may not mislead an offeror through the framing of a discussion question into responding in a manner that does not address the agency's actual concerns, or otherwise misinform the offeror concerning a problem with its proposal. See, e.g., *M.A. Mortenson Co.*, B-413714, Dec. 9, 2016, 2016 CPD ¶ 361 at 8-9; *Metro Mach. Corp.*, B-281872 *et al.*, Apr. 22, 1999, 99-1 CPD ¶ 101 at 6. An agency, however, only needs to lead an offeror into the areas of its proposal requiring amplification or revision; all-encompassing discussions are not required, nor is the agency obligated to "spoon-feed" an offeror as to each and every item that could be revised to improve its proposal. *Advanced Constr. Techniques, Inc.*, B-404847.6, Jan. 25, 2012, 2012 CPD ¶ 54 at 8. We do not find that the agency conducted misleading discussions with Navitas.

In the first round of discussions, the agency identified an area of concern related to work area 2 of the SOW, which describes regulatory oversight and support activities for DSMB/SO related activities. Navitas was asked the following discussion question:

- Question No. 3b: In the absence of an NIA provided electronic system for [data and safety monitoring boards/safety officers (DSMB/SO)] management, what system or methodology is [Navitas] proposing to use to manage DSMB/SO documents? Is the system or methodology proposed compliant with all applicable requirements (e.g., [Federal Information Security Modernization Act], 21 C.F.R. [p]art 11 . . .)? Please clarify the costs related to such a system and include these costs in the budget.
 - i: If [Navitas] has not proposed the use of a system, how does [Navitas] propose to manage DSMB/SO documents in a manner that is compliant with applicable requirements?
 - ii: If no proposed system, what recommendations can [Navitas] provide to NIA to increase efficiencies with respect to [Work Area] 2? Please provide any budget implications above and beyond what [Navitas] proposed to adopt these recommendations.

AR, Exh. 3e, First Req. for Proposal Revisions at 2.

In response, Navitas proposed to use a [DELETED] for DSMB/SO document management; the protester asserted that [DELETED] was compliant with 21 C.F.R. part 11. See AR, Exh. 3f, Navitas Resp. to First Req. for Proposal Revisions at 14-15. In its request for final proposal revisions, the agency explained that [DELETED] is not compliant with 21 C.F.R. part 11, and asked Navitas "[b]ased on this, please provide an updated response to this question." AR, Exh. 3o, Second Req. for Proposal Revisions

at 3; *see also id.* (also inviting Navitas to otherwise address how it would manage the DSMB/SO documents in a compliant manner).

In response, Navitas represented that “[i]f it is determined that [DELETED] needs to be 21 CFR Part 11 compliant, [Navitas] will provide NIA with [DELETED] cloud-hosted controlled [DELETED] to support NIA DSMB/SO document management and meet the regulatory requirements,” or in the alternative proposed to implement other commercial-off-the-shelf solutions that would need to be separately priced. AR, Exh. 3q, Navitas Resp. to Second Req. for Revised Proposal at 16. The agency subsequently assessed a weakness for the protester’s revised approach. Specifically, the agency found that Navitas did:

[N]ot provide a clear-cut solution for NIA DSMB document storage and management, but only proposes that if NIA needs a 21 CFR part 11 compliant site, [Navitas] will provide [DELETED] cloud hosted controlled [DELETED] to support DSMB/SO document management. The time to develop a new site and the time to make it compliant with the requirements of 21 CFR part 11 are not presented and the time needed to build such a site will delay [Navitas’s] ability to support NIA monitoring boards using compliant document management solutions. [Navitas] proposed an alternative solution in that NIA could choose to use a commercial off the shelf system, which has not been budgeted for in this proposal, which would also add costs, require time for set up and configuration. This is critical as NIA does not currently have a system to store/manage DMSBs and require the CRSS contractor to provide the solution.

AR, Exh. 4k, Final Proposal Eval. Report at 16.

In its protest, Navitas claims that these discussion questions misled the protester into believing that providing a database for management of DSMB/SO documents was now a solicitation requirement, and the agency effectively coerced it into proposing a database solution. Supp. Protest at 20. Contrary to the protester’s arguments, nothing in the discussion question, quoted above, supports its interpretation that it was required to provide a database for DSMB/SO management. Rather, based on the record presented, we find that the discussion question asked what system or methodology--not what database--Navitas would use in the absence of an NIA provided electronic system to manage DSMB/SO documents.

In this regard, we have explained that while an agency may not, in conducting discussions, coerce an offeror into raising its prices or altering any other aspect of its proposal, we will not find coercion in discussion where, as here, an agency provides information to an offeror which accurately reflects the agency’s concerns, and leaves it to the offeror regarding how to respond. *General Dynamics Info. Tech., Inc.*, B-420589, B-420589.2, June 15, 2022, 2022 CPD ¶ 149 at 22. Moreover, an agency’s discussions are not misleading or otherwise improper merely because an offeror makes an

independent business judgment that it later regrets. *Wolverine Tube Inc. d/b/a Wolverine Indus.*, B-418339.4, B-418339.5, July 26, 2022, 2022 CPD ¶ 219 at 9; *NOVA Dine, LLC*, B-420454, B-420454.2, Apr. 15, 2022, 2022 CPD ¶ 101 at 7. Here, the record shows that the agency sought information from Navitas on how it proposed to manage relevant documents, and Navitas elected to propose the use of a database without sufficient supporting implementation details, and, thus, there is no basis to conclude that the agency misled the protester.¹³

Next, Navitas alleges that the agency misled the protester as to the true nature of its concerns with the protester's proposed approach to data mining. In the first round of discussions, the agency asked:

- Question No. 9: Please elaborate on your organizational experience with data mining and analysis of data in electronic systems to identify trends as well as gaps. Please elaborate on the proposed staffing level and the considerations on which that proposed level is based.

AR, Exh. 3e, First Req. for Proposal Revisions at 4.

In response, Navitas addressed its corporate experience as well as its proposed level-of-effort for data science and related support. AR, Exh. 3f, Navitas Resp. to First Req. for Proposal Revisions at 32-36. The protester also introduced its proprietary [DELETED], which it proposed would provide [DELETED]. *Id.* at 32. Navitas, however, explained that it had not priced the use of the system in its business proposal subject to further discussions with NIA. *Id.* at 36.

In its second round of discussions, the agency noted that: “[DELETED] has no plans to capture and access [DELETED] as they are not the Sponsor for studies that they fund. Thus, there is no intent to have real-time access to clinical trial data.” AR, Exh. 3o, Second Req. for Proposal Revisions at 6. The letter further asked Navitas to “provide details on the proposed staffing levels and the rationale for the proposed staffing.” *Id.* In response, Navitas explained that it would provide its platform to NIA for free for performance of the task order, and otherwise described its data mining and analysis strategy plan and proposed staffing. AR, Exh. 3q, Navitas Resp. to Second Req. for Proposal Revisions at 26-29.

The agency ultimately assessed a weakness in Navitas's proposal based on concerns regarding the lack of detail regarding the basis for the protester's approach to data mining. Specifically, the agency found that:

¹³ To the extent that the protester contends that the agency's insistence that it was the contractor's, as opposed to the agency's, responsibility to provide a document management system was patently inconsistent with the solicitation, such an objection is untimely raised at this time. See, e.g., *Pacific Architects and Engineers, Inc.*, B-274405.2; B-274405.3, Dec. 18, 1996, 97-1 CPD ¶ 42 at 5-6 (protest untimely when protest grounds learned during discussions but protest not filed until after award).

[Navitas] continues to talk about NIA data mining needs but do[es] not explain what data they are expecting to mine; specifically, they refer to a [DELETED] they will offer that can serve as the NIA data repository and to collect 'large volumes of NIA clinical research and study data' but this does not seem to be referring to the type of data discussed in [the] SOW so it is unclear what the data mining tools introduced will do for the [Work Area 3] as written in [the task order] (NIA does not collect study data, for example). It seems that steps 1-3 [of Navitas' approach] are expecting to use [DELETED] from across NIA trials. It is not CROMS data that are referenced (as CROMS already does the steps and data [that] are already centralized). It was very unclear why these tools are proposed.

AR, Exh. 4k, Final Proposal Eval. Report at 17 (internal citations omitted).

Navitas asserts that it was misled into thinking that this discussion question sought information about its data mining capabilities rather than addressing the agency's true concerns as to the data proposed to be mined. We do not agree. In this regard, the agency had concerns with respect to the introduction of a data platform in response to its initial discussion question seeking information about the protester's corporate data mining experience. The agency's second discussion letter clarified that it did not understand the basis for the proposed platform, as it appeared that a significant portion of the data identified with respect to the platform's collection was not relevant to the data to be collected under the resulting task order. The agency then requested that the protester provide its rationale for its proposed staffing with respect to data mining. We think this was sufficient to lead the protester into the area of its proposal requiring amplification; namely, the basis for why the protester intended to staff personnel to perform data mining activities. In sum, our review of the record gives us no basis to question the agency's conduct of discussions with the protester.

Past Performance Factor

Finally, Navitas alleges that the agency's past performance evaluation was unreasonable. Supp. Protest at 41-42. According to the protester, the agency improperly utilized an unstated evaluation criterion by disproportionately focusing on the size of its own and its subcontractor's prior contract references. *Id.* at 42. In this regard, the record reflects that while the agency found Navitas and its subcontractor demonstrated "some relevant past performance related to a portion of the scope of the contract, it is not comparable in size," and, therefore, "caution may be warranted regarding the possible award and performance risk may be assessed further due to the complexity and size of the proposed type of contact." AR, Exh. 4l, Past Performance Eval. Report at 9; see also Exh. 4j, Source Selection Decision Mem. at 23 (finding Navitas "represents a higher risk as they have no relevant past performance in contracts of the same size and complexity"). In its comments, the protester alleges that use of this unstated evaluation criterion unreasonably led to a finding of performance risk. Protester's Comments at 26.

The evaluation of past performance, including an agency's determination of the relevance and scope of a firm's performance history to be considered, is a matter of agency discretion, which we will not find improper unless unreasonable, inconsistent with the solicitation criteria, or undocumented. *D&G Support Servs., LLC*, B-419245, B-419245.3, Jan. 6, 2021, 2021 CPD ¶ 15 at 8. We have previously explained that where, as here, a solicitation specifically requires that offerors submit the dollar values of prior efforts, and the solicitation explains that the efforts will be evaluated for similarity to the current requirement, it is not irrational or inappropriate for the agency to consider the dollar value of prior efforts. *Insect Shield Mfg., LLC*, B-408067.3, Aug. 8, 2013, 2013 CPD ¶ 235 at 3-4; *ITT Electronic Sys. Radar, Reconnaissance & Acoustic Sys.*, B-405608, Dec. 5, 2011, 2012 CPD ¶ 7 at 12-13.

As stated previously, the agency would assess the risks associated with each offeror's record of performance including the likelihood of successfully performing the solicited requirements as indicated in its record of past performance. See AR, Exh. 2b, RFP at 87. In this regard, the RFP specifically required offerors to identify contracts "that [were] similar in nature to the solicitation [SOW]," including identifying the total contract value for each reference.¹⁴ *Id.* at 62. On this record, we find no basis to object to the agency's consideration of the relative magnitude of Navitas's prior past performance.

Furthermore, we find no basis to sustain the protest based on Navitas's disagreement as to the weight afforded to magnitude. As to the assessment of performance risk, the record indicates that the agency's assessment was based on the size, scope, and complexity of Navitas's and its subcontractor's prior performance and the likelihood of its successful performance of the size, scope, and complexity of the solicited services. See, e.g., AR, Exh. 4l, Past Performance Eval. Report at 6 (finding that Navitas's past performance was "relevant, represents a relative low performance risk, and indicates a very good likelihood of successful performance," but also finding that "although the offeror has some relevant past performance as related to a portion of the scope of the contract, it is not comparable in size," and "[a]s a result, there is not a high level of confidence that Navitas could perform successfully on a contract of similar size, complexity and scope since comparable information was not provided"). Navitas's disagreement with the agency's judgment does not establish that the evaluation was improper. *Chenega Fed. Sys., LLC*, B-417037.2, Sept. 6, 2019, 2019 CPD ¶ 314 at 7; *L-3 Nat'l Sec. Sols., Inc.*, B-411045, B-411045.2, Apr. 30, 2015, 2016 CPD ¶ 233 at 12.

¹⁴ Additionally, we note that the RFP provided that "[t]he same type of organizational experience and past performance data should be submitted," AR, Exh. 2b, RFP at 84, and that for organizational experience offerors were specifically directed to "[d]iscuss recent prior experience . . . in conducting projects that are similar in scope, size, and complexity to the requirements outlined in the [SOW]." AR, Exh. 2c, RFP attach. 5, Additional Technical Proposal Instructions at 19.

The protest is denied.

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General Counsel