

JUSTIFICATION
FOR AN EXCEPTION TO FAIR OPPORTUNITY

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Procurement Acquisition and Logistics
Technology Acquisition Center
23 Christopher Way
Eatontown, NJ 07724
2. Description of Action: This proposed sole source delivery order against National Aeronautics and Space Administration (NASA) Solutions for Enterprise-Wide Procurement (SEWP) V Government-Wide Acquisition Contract (GWAC) NNG15SD34B is for a firm-fixed-price delivery order for an IRBNet software-as-a-service (SaaS) solution with Minburn Technology Group, 10113 Minburn Street, Great Falls, Virginia 22066.
3. Description of the Supplies or Services: VA, Veterans Health Administration (VHA), Office of Research, Protections, Policy and Education, Office of Research and Development has a requirement for an electronic research administration platform across VHA to support review and oversight of clinical innovation and the research portfolio for bench laboratory, animal testing and human research studies. The platform will also support the collection of metrics across VHA on efficiency and regulatory compliance and allow VHA to consolidate current disparate metric collection actions. The period of performance shall include a 12-month base period with four, 12-month option periods and one optional task. The overall period of performance shall not exceed 60 months and the total estimated value of the proposed action is [REDACTED], inclusive of execution of options.
4. Statutory Authority: The statutory authority permitting an exception to fair opportunity is Section 41 U.S.C. 4106(c)(2) as implemented by the Federal Acquisition Regulation (FAR) Subpart 16.505(b)(2)(i)(B), entitled "Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized."
5. Rationale Supporting Use of Authority Cited Above: Currently, 31 VA medical centers (VAMC) have individually contracted four different commercial-off-the-shelf (COTS) institutional review board (IRB) applications to manage and maintain a record of regulatory compliant research review through all required federal and VHA committee processes. The systems currently in use are; IMedRIS (IRIS), Tech Software (IRBManager), Research Dataware (IRBNet), and Huron (IRB8). Beginning January 20, 2020, all Federal agencies must adhere to a national mandate to minimize duplicative regulatory reviews as specified in the revised Common Rule (38 CFR 16.114 (b)(1) as codified by VA) that will require the flexibility to use a single IRB review for collaborative (i.e., multi-institutional) studies. Published research on the review and approval processes of multi-institutional research demonstrates that studies undergoing multiple individual IRB reviews show a negative effect on the science and the protection of the human subject participants. Therefore, 20 Federal Agencies, including VA, adopted the new provision for single IRB review for collaborative studies. The Agencies

were given three years to implement systems to support the mandate. Through the acquisition of this flexible research platform that can be rapidly implemented, VHA will be well positioned to meet the requirements of regulation 38 CFR 16.114 (b)(1) that states: "Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States." The proposed source for this action is Minburn Technology Group, 10113 Minburn Street, Great Falls, Virginia 22066. Minburn Technology is the sole distributor of the IRBNet platform other than contracting directly with Research Dataware LLC, the owner of IRBNet. Minburn Technology Group is currently providing the IRBNet platform to six VHA sites. This proposed action would create an enterprise-wide solution encompassing all VAMCs. IRBNet has a 10-year proven performance record in VHA and provided an enterprise solution for Department of Defense (DOD) medical research. IRBNet is the only commercial product that has proven itself as an enterprise solution for a large medical organization. IRBNet has already begun the Authority to Operate (ATO) process through VHA, Office of Information Technology for the sites currently operating on its software and has obtained an ATO for those specific site locations. IRBNet is aware that they will require a VA-wide ATO in order to implement an enterprise solution.

IRBNet's platform is different from other commercial systems in that it has the flexibility to operate as a committee-based platform with unlimited routing opportunities rather than a form-based platform with programmed routing. Form based products also require concurrence from user groups to create the forms and designate the routing in advance of the process. Changes to the designated form-based process will alter metrics and require retooling by the vendor. Startup times to form creation can last up to one year in complex organizations such as VHA. With 110 independent VHA research sites currently processing research documents without standardized forms, templates and process, a form-based solution will not meet the requirements for VHA. IRBNet offers a committee-based solution where locally developed forms can be attached. Those forms do not dictate routing. Routing is done through administrative users on a case by case basis which gives the system a flexibility that is not an option in other products, as demonstrated by the market research set forth below. Metrics based forms can be developed centrally and do not affect routing. Standardized forms can be created within the IRBNet system but they are not tied to predetermined routing. This flexibility is an essential feature to the Government's requirements.

As a committee-based solution rather than a form-based solution like the competitors, IRBNet start up time relies solely on the complexity of the number of committees at each VHA medical center conducting research. Startup can be achieved in days to weeks once an enterprise Authority to Operate (ATO) on a Federal Risk and Authorization Management Program (FEDRAMP) certified commercial platform is secured. Workspaces and decisions on committee outcomes are standardized centrally ensuring consistent metrics across VHA. Market research revealed that coming to consensus on common forms/templates would take months and local changes that can be made by each local authority to competitor products would undermine the strategic metric collection that is the fundamental basis of the VHA's requirement and would undermine timely compliance with the mandate in 38 CFR 16.114 (b)(1).

Market research set forth below indicates that other companies' similar products lack the committee-based platform feature; as such, they do not meet, or cannot be modified to meet, the agency's needs. Furthermore, customization of other products will cause an unacceptable delay in meeting the VHA requirements.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. In accordance with FAR 5.301 and 16.505(b)(2)(ii)(D), the award notice for this action will be synopsisized on the Federal Business Opportunities Page and the justification will be made publicly available within 14 days of award.

7. Actions to Increase Competition: The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research: The Government's technical experts conducted market research by reviewing other similar software. Market research began in August 2018 and is continuously being conducted, as recently as May 2019. Besides Research Dataware (IRBNet), the other similar software reviewed included IMedRIS (IRIS); Key Solutions (eProtocol), Huron (IRB8), and Tech Software (IRBManager). The Key Solutions (eProtocol) and Huron (IRB8) products were not pursued because both are form based platforms without the required flexibility, such as the ability to send to ad hoc IRBs. The system flows for both products need to be changed if new IRBs or committees are added to the workflow. In addition, both products have no proven implementations of an enterprise-wide system and both require that a single submission form be created to drive the system. These single forms require anywhere from months up to one year to design. As such, VHA will not be able to meet the required deadlines. The Huron (IRB8) product is the system used by the Department of Energy (DOE) and operates in a "multi-tenant" mode. DOE invested substantial time and money in customizing the product and helping the company develop the multi-tenant mode. The COTS product is now made with this multi-tenant feature but there is no ability to partition sites from one another, which is not acceptable to the scientists and industry partners who are trying to protect intellectual property. DOE informed VA that it can program the partitions by further customizing the system, however, VHA requires a COTS solution that can be efficiently put in place without delays associated with customization. The IMedRIS (IRIS) product was not pursued due to the poor reviews received from Department of Defense (DOD) as an enterprise tool. DOD has been attempting to implement the IMedRIS (IRIS) product as an enterprise solution for the last four years and is still struggling to bring its research sites online. After four years and thousands of hours of dedicated implementation time, DOD still has no ability to oversee its research portfolio through the IMedRIS (IRIS) product. Since VHA requires an enterprise wide solution, this product is not an option.

Based on reviews of these products, the Government's technical experts determined only IRBNet can deliver an enterprise-wide COTS solution that does not require substantial customization.

9. Other Facts: None.

10. Technical and Requirements Certification: I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

[REDACTED]

[REDACTED]

11. Fair and Reasonable Cost Determination: I hereby determine that the proposed delivery order action will represent the best value to the Government consistent with FAR 16.202-2(c). NASA SEWP determined that the catalog prices on its GWACs are fair and reasonable. Finally, price analysis shall be conducted by comparing the successful quote to the Independent Government Cost Estimate.

[REDACTED]

[REDACTED]

12. Procuring Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief.

[REDACTED]

[REDACTED]

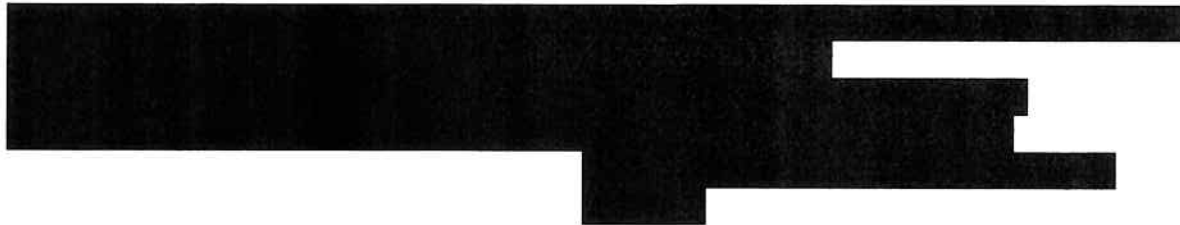
13. Legal Sufficiency Certification: I have reviewed this justification and find it adequate to support an exception to fair opportunity and deem it legally sufficient.

[REDACTED]

[REDACTED]

Approval

In my role as Head of the Contracting Activity, based on the foregoing justification, I hereby approve the acquisition of IRBNet software application on an other than fair opportunity basis pursuant to the authority cited in paragraph 4 above, subject to availability of funds, and provided that the property and services herein described have otherwise been authorized for acquisition.

A large black rectangular redaction box covering the signature and name of the approving official.