

JUSTIFICATION AND APPROVAL FOR OTHER THAN FULL AND OPEN COMPETITION

Acquisition Title: Office of Extramural Research (OER) Agile Software Development Support Services

Agency: NIH

Acquisition Year (FY): 2023

Author and Title: Patricia A. Gaines, Project Officer

2. Description of Action:

Nature:	<input type="checkbox"/> New Requirement	<input type="checkbox"/> Follow-on Requirement	
	<input checked="" type="checkbox"/> Modification to Existing Purchase Order/Contract Number:		75N94019C00013
Pricing:	<input type="checkbox"/> Firm-Fixed Price	<input type="checkbox"/> Time & Materials	Cost Cost plus fixed fee
	<input type="checkbox"/> Other:		
Funds:	<input checked="" type="checkbox"/> OMA	<input type="checkbox"/> Other Funds:	

Name of Proposed Contractor(s): Leidos, Inc.

Street Address: 11251 Roger Bacon Dr.

City, State, Zip: Reston, VA 20190

3. Description of Services or Supplies:

Basis for Approval (FAR 6.303-1(d)):	<input checked="" type="checkbox"/> Individual Basis	<input type="checkbox"/> Class Basis
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The total estimated value of the proposed action, including all options is \$52,039,335.40

The purpose of this action is to obtain continuation of the current OER Agile Software Development Support Services for eRA for 12-months while the competition effort is ongoing. This contract was awarded under Solicitation No. 75N97019R00003 and was titled, "OER Software Design and Development". The NAICS Category is 541511 - Custom Computer Programming Services. The Solicitation was Posted on June 14, 2019, by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (HHS- NIH - NICHD). This is a modification to allow for a bridge between the current contract 75N94019C00013 awarded to Leidos, Inc and the new competition. The original period of performance was Sept. 30, 2019 - Sept 29, 2024, for a total dollar value of \$149,959,860. Due to unforeseen circumstances (See #10), the contract will not be awarded by the current contract's estimated end date of June 30, 2023. This bridge contract will allow more time for completion of the acquisition and competitive award of the larger contract estimated to be about \$300 million.

eRA offers vital solutions to manage the receipt, processing, review, award reporting and monitoring of \$40 billion in research and non-research grants awarded annually by 24 NIH Institutes and Centers as well as other grantor agencies in support of the collective mission of improving human health.

eRA is a validated Grants Management Quality Services Management Office (QSMO) shared service provider ((<https://ussm.gsa.gov/marketplace/grm/>) for the federal government. eRA provides information technology solutions and services for the full life cycle of grants administration for the NIH as well as the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMSHA), Veterans Administration (VA), and the Department of Commerce (DOC).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

eRA is classified as a mixed financial system. eRA routinely undergoes annual audits. Nearly 80% of the NIH budget flows through eRA systems. The stability and security of eRA systems is critical to the ability of NIH and its agency partners to fulfill their missions.

eRA develops and supports multiple complex systems that:

- ☐ Record, review, and process over 172,000 applications and awards each year.
- ☐ Support over 443,000 active users and close to 27,000,000 logins each year.
- ☐ Support over 60,500 reviewers and more than 3,160 review meetings.
- ☐ Process over 270,000 reviewer critiques.
- ☐ Administer more than 72,450 awarded competing and non-competing grants.
- ☐ eRA systems are used by over 263,000 applicants and grantees at over 38,000 institutions worldwide.

The system supports the Federal Business Lifecycle – Grants Management from GRM.010 through GRM.040 as documented at <https://www.ussm.gov/fibf-gm/>.

eRA's focus is on supporting the mission of serviced agencies by providing systems to electronically manage and report on grants in a way that:

- ☐ Ensures strong system and data security.
- ☐ Provides flexibility to respond to the unique business needs of NIH and its federal agency partners.
- ☐ Provides a system that promotes effective and efficient, end-to-end management of federal grants.
- ☐ Provides dependable, responsive system availability with 24 x 7 on-call support.
- ☐ Continually enhances the eRA system to reduce the administrative burden on the user community as well as agency staff.
- ☐ Maximizes efficiencies.
- ☐ Provides a strong and scalable infrastructure.
- ☐ Is responsive to evolving customer needs.
- ☐ Employs sound management and secure controls.
- ☐ Provides a positive user experience

The purpose of the acquisition is to provide specific support for the following Agile Software Development Support Services tasks that are critical for eRA and its stakeholders:

- o Design- includes system enhancements of existing systems, modernization and development of new systems and features
- o Implementation (Note: eRA is responsible for 60+ major systems)
- o Application Testing - Junit, Functional Testing, Integration Testing, Security Testing, Supporting Load and Performance Testing, 508 Compliance Testing
- o Application Security - Application security demands continue to increase including more strict remediation timelines, government mandates, continuous monitoring via application security scanning tools
- o User Experience (UX) – Essential work as a government wide system service provider including standardization across major eRA systems

- o Project Planning Support
- o Requirements Analysis Support
- o Project Integration Management/ Development Support
- o Enterprise System and Production Support
- o Documentation Support
- o Training Support
- o eRA Infrastructure Support
- o Website development

This is a modification to contract number 75N94019C00013 awarded to Leidos, Inc which will be a bridge to a new competitive contract award. The original period of performance was Sept. 30, 2019- Sept. 29, 2024, for a total dollar value of \$149,959,860. The revised contract end date is approximately June 30, 2023, due to significant increases in software development needs over the past several years from NIH and the various agency partners that have expended the total dollars (ceiling) faster than anticipated (see #10).

4. Authority and Rationale: Identify the statutory authority, FAR title and FAR citation permitting other than full and open competition. It may be one of the following most commonly used citations by the operating divisions of the Department of Health and Human Services (HHS), but other exceptions may apply per [FAR Subpart 6.3](#).

Actions other than simplified acquisition procedures (select only one and provide an explanation):

- ☒ **FAR 6.302-1:** Only one responsible source and no other supplies or services will satisfy agency requirements, 41 U.S.C. 3304(a)(1)

The incumbent contractor has extensive knowledge and software development experience with the custom code, design, implementation, security, testing and support of major eRA systems including but not limited to:

- Account Management System (AMS): Used to create, manage, and search existing accounts in eRA system
- Agency Data Integration Application (Manage Agency Data): Used by eRA partner agencies to manage their data in eRA system
- Alert Module: Used by OER users to create, enter and manage alerts associated with NIH grants and grant applications to keep them out of permanent storage
- Animal Assurance Record Management System (AARMS): Used to manage animal welfare assurance records and related correspondence
- Archive Exclusion System (AES): Allows users to apply record holds to grants and applications to keep them out of permanent storage.
- Assignment Change Request (ACR): Used to change the assignment of grant applications after submission
- Awaiting Receipt of Application (ARA): Used to electronically track and link information received prior to submission, to an application once it's submitted
- Certificates of Confidentiality (CoC): Protects the privacy of research subjects
- Checklist Management: Used by Grants Management and Program Staff for reviewing and entering assurances and prerequisites that require approval
- Code Request Information Management System (CRIMS): Used for searching and requesting activity codes
- Committee Management Module (CMM): Used to manage critical administrative processes associated with setting up peer review, special emphasis panels and advisory councils
- Contract and IAA Management System (CIMS)
- Electronic Council Book (ECB)
- electronic Tracking and Analysis (eTA)
- eRA Commons: Used for grant applicants, grantees, federal NIH staff and grantor agencies to share information related to grants
- eRA Database Change Password
- eRA Search
- Financial Conflict of Interest (FCOI)
- Foreign Award and Component Tracking System (FACTS)
- Funding Opportunity Announcement Module (FOAM)
- GM Workbooks: Used by the grants management community for calculating and validating the appropriate amounts for all aspects involved in a grant award
- Grant Folder (GF): Serves as the main entry point to view official grants related documents for a particular grant application.
- Grants Closeout Module (GCM)
- Grants Management (GM): Used for grantor agencies to document the administrative review in conjunction with issuing grant awards
- Human Subjects System (HSS)
- Institution Profile (IPF): Used to maintain institutional profiles of organizations involved in research projects that are external to NIH
- Intent to Pay (ITP)
- Internal Referral Module (IRM)
- Internet Assisted Review (IAR)
- Manual Categorization System (MCS): Allows IC and SIA users to categorize and report medical research funding
- Non-Discretionary Grants Module (NDGM) - SAMHSA ONLY
- Paperwork Reduction Act Clearance System (PRACS)
- Pay Plan Module
- Payback Module
- Peer Review (REV): Used to facilitate the initial evaluation of research grant applications in a secure environment by peer review groups, composed of scientists who are experts in the relevant fields of research

- Person Module
- Program Mgmt. Module (PMM): Designated for Program Officials to manage portfolios and the end-to-end grant lifecycle
- Query, View, Report (QVR): Used for NIH staff to search, view and retrieve detailed information about grant applications and awards
- Real Time Meeting Status (RTMS): Allows Program Officials to track the discussion status of grant applications in their portfolio at review meetings in real time
- Receipt and Referral (eRR): Used as a central receipt point for all competing NIH grant and cooperative agreement applications. Also used by NIH review staff in the assignment, assessment, and review of grant applications
- Research, Condition and Disease Categorization (RCDC): Used by NIH to categorize its funding in medical research at the end of each fiscal year
- SPIRES: A database of scientific publications resulting from NIH supported research, both extramural and intramural. Used to automatically map publications from the NLM PubMed database to the respective grants.
- Subproject Management System (SMS)
- Terms and Conditions Module (TCM) for SAMHSA: Enables SAMHSA ICs to define and manage structured terms and conditions that can be applied to grants they administer
- Thesaurus Management System (THMS)
- Extramural Trainee Reporting and Career Tracking (xTRACT)
- xTrain: The Extramural Training Module allows grantees to electronically submit and agency staff to process the appointment and termination notices for individuals on research training grants, career/education awards, and individual fellowships

The above eRA systems are very complex, unique as integrated together [REDACTED] and must continue with same Contractor. The incumbent contractor is the only responsible source who can provide the required services due to the above unique and interrelated major systems. The incumbent contractor is essential to the Government's requirements and other companies' lack the integrated system features to meet the NIH's needs.

It would be very expensive (estimated at 20% to 30% of the annual costs of the contract, not including the opportunity costs to NIH because of resulting delays) to become familiar and proficient with the many components of the above eRA integrated systems, IT architecture, security processes and documentation requirements, and understand current needs and history. For eRA's and NIH's mission it is critically important to have continuity in the level of support and expertise that is provided by Leidos and its personnel. Consistency and continuity of the support services provided under the current contract are essential to avoiding disruption [REDACTED]. A disruption will put eRA at risk of not being able to maintain and secure the Grant data for NIH and other partner

[REDACTED]
[REDACTED]
[REDACTED]

Also, due to these very complex systems we need additional time to perform market research and to perform proper competition that will allow offerors to be prepared to come on board and be successful.

☐ [FAR 6.302-2](#): Unusual and compelling urgency, 41 U.S.C. 3304(a)(2)

☐ [FAR 6.302-5](#): Authorized or Required by Statute, 41 U.S.C. 3304(a)(5)

☐ Other (See [FAR Subpart 6.3](#) for additional authority)

5. Agency Actions to Take or Remove Barriers That Led to Other Than Full and Open Competition (If applicable):

This is a modification to contract number 75N94019C00013 that was competitively awarded under Solicitation No. 75N97019R00003. An announcement will be posted on SAM.gov as required by FAR Subpart 5.2.

6. Bridge Contracts:

7. Actions to Increase Competition:

This is a modification to contract number 75N94019C00013 that was competitively awarded under Solicitation No. 75N97019R00003. An announcement will be posted on SAM.gov as required by FAR Subpart 5.2.

8. Market Research:

A Small Business Sources Sought Notice SS-92211-SB for this requirement was published through NITAAC CIO-SP3 SB on January 11, 2023. The reviews concluded that the interested potential offerors lacked the capability to perform the work described in the Sources Sought Notice. The lack of capable parties, albeit small businesses, further show Leidos is currently the only source capable of providing this service. We anticipate additional efforts will be made to prepare the market for the release of the solicitation, including its inclusion on the Procurement Forecasts and possibly a draft RFP/RFQ.

9. Procurement History:

Purchase order or contract number: 75N94019C00013

Was action competed?	<input checked="checked" type="checkbox"/> Yes	<input type="checkbox"/> No
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If action was not competed, state the cited authority, summarize rationale, and describe the actions that were supposed to be taken to increase competition and the results thereof:

10. Additional Information to support the justification:

It was anticipated that the award of a new five-year contract would be made prior to expiration of the current contract (funding).

eRA has been officially designated as a Federal government Grants Management Quality Services Management Office (QSMO) provider and the demand for eRA systems increased due to the unanticipated addition of federal agency customers. eRA will plan for future growth, but demand cannot be realistically predicted since it is driven by prospective agencies interested in using eRA services, and as such, it is dependent on their own internal business needs and objectives. The scope, complexity, and timeline for onboarding a potential partner varies greatly, from small offices looking for a very limited set of services with a quick turnaround, to entire Departments looking to utilize the full breath of eRA services through a multi-year phase approach. Future contract acquisitions will take these factors into consideration so that eRA can meet the federal grants mission and OMB mandate. That increase in current and potential future demand has led to an increase in the need to keep eRA systems up to date and secure, which has in turn led to an increase in auditing and assessments.


The unique and changing needs of NIH and its Agency partners, to include changes related to COVID, Grants Closeout, Loan Repayment, UEI, R&D Contracts and other important policy changes, has resulted in a more rapid expenditure of funds on the contract than was previously anticipated.

Finally, in order to meet all internal processes required for an acquisition of this magnitude of this effort, more time is necessary. This modification will allow more time for completion of the acquisition and award of the larger contract estimated to be over \$300M. The modification will increase the ceiling to \$52,000,000.00.

eRA, as the grants management system service provider to NIH and other government agencies, would be severely impacted by any break in service for software development support services. The risk of grant applications being submitted and processed would be at risk. eRA would not be able to fulfill its mission to provide grants management systems and services to NIH and other government agencies.


An interim contract with Leidos will eliminate the risk of lapse in service and additional expense to the government during the interim period, to allow more time for the new five-year contract to be awarded. A 12-month period of performance is the minimum acceptable period to ensure the competition and contract award is completed in accordance with HHS and NIH acquisition policies.

11. Technical / Requirements Certification: *By my signature below*, I certify that the supporting data included in this J&A is accurate and complete.


<u>Program Manager</u>	
Name:	Patti Gaines
Position Title:	Director, Division of Development and Customer Engagement
Email address:	gainesp@od.nih.gov
Phone:	(301) 675-3037
<u>Program Manager Supervisor (or one level above Program Manager)</u>	
Name:	Inna Faenson
Position Title:	eRA Director
Email address:	faensoni@od.nih.gov
Signature:	Inna Faenson -S  Digitally signed by Inna Faenson -S Date: 2023.05.24 10:48:06 -04'00'
Date:	05/22/2023

12. Fair and Reasonable Price/Cost Determination: As Contracting Officer, by my signature below, I hereby determine that the anticipated price/cost to the Government for this contract action will be fair and reasonable.

An Independent Government Cost Estimate (IGCE) was developed using historical expense data covering year of expenses incurred, recent contractual efforts for the follow-on requirement, which is the same (or similar) as the current effort, technical knowledge by the Program Office regarding the type and number of personnel required and their labor rates. This is fair as the contract was competitively awarded. Additional Price analysis will be performed to evaluate the labor and price to the government's estimated labor hours and price estimate to determine that the price is fair and reasonable.

Name:	Donald Ledwig	Phone:	301-443-8278
Signature:	Donald E. Ledwig -S  Digitally signed by Donald E. Ledwig -S Date: 2023.05.24 11:02:21 -0400	Date:	5/24/2023

13. Contracting Officer's Approval (Required for proposed contract not to exceed \$700,000 (value calculated including all options)): I hereby certify that this justification is accurate and complete to the best of my knowledge. I approve this justification subject to availability of funds, and provided that the services and supplies herein described have otherwise been authorized for acquisition.

Name:	Donald Ledwig	Phone:	301-443-8278
Signature:	Donald E. Ledwig -S  Digitally signed by Donald E. Ledwig -S Date: 2023.05.24 14:22:16 -0400	Date:	5/24/2023

14. Legal Review:

15. OPDIV Competition Advocate Approval (Required for proposed contract over \$700,000 but not exceeding \$13.5 million (value calculated including all options)):

I have reviewed this justification and find that it adequately supports other than full and open competition.

Name:	Dr. Kathryn Partin, Director of Research	Phone:	(301)451-7764
Signature:	Kathryn M. Partin -S <small>Digitally signed by Kathryn M Partin -S Date: 2023 05 25 17:34:00 -04'00'</small>	Date:	

16. Office of Small and Disadvantaged Business Utilization Review: (Required for contracts exceeding \$68 million (value calculated including all options)):

Concur:	<input type="checkbox"/>	Non-Concur:	<input type="checkbox"/>
Name:		Phone:	
Signature:		Date:	

17. OPDIV HCA Approval (Required for proposed contract over \$13.5 million but not exceeding \$68 million (value calculated including all options)):

Name:	"for" Diane J. Frasier, Director, Office of A	Phone:	(301) 496-4422
Signature:	Phillip D. Osborne -S <small>Digitally signed by Phillip D Osborne -S Date: 2023 05 25 08:52:15 -04'00'</small>	Date:	

18. Department Competition Advocate (Required for contracts exceeding \$68 million (value calculated including all options)):

Concur:	<input type="checkbox"/>	Non-Concur:	<input type="checkbox"/>
Name:		Phone:	
Signature:		Date:	

19. HHS Senior Procurement Executive (SPE) Approval:

Based on the foregoing justification, I hereby approve other than full and open competition for the above stated procurement, subject to the availability of funds, and provided that the services herein described have otherwise been authorized for acquisition.

State supplies/services being procured:

State the full statutory authority and FAR cite and title, consistent with paragraph 4, e.g. 41 U.S.C. 3304:

Name:		Phone:	
Signature:		Date:	