Justification and Approval for Sole Source

"Source Selection Information – see FAR 2.101 and 3.104"

1. Identification of the agency and contracting activity.

a. Federal agency and contracting activity.

Department of Health and Human Services (DHHS)
Office of the Secretary (OS)
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Biomedical Advanced Research and Development Authority (BARDA)

b. Sponsoring organization.

Division of Clinical Development (DCD)
Clinical Studies Network (CSN)

c. Project Officer information.

Marcy Beth Grace Ph.D.
Thomas P. O'Neill Federal Building
200 C Street SW
Room 21J17
Washington, DC 20024
marcy.grace@hhs.gov
(202) 527-0423

2. Nature and/or description of the action being approved.

a. Acquisition purpose and objectives.

The Biomedical Advanced Research and Development Authority (BARDA) intends to issue modifications to extend contract ordering periods for the Indefinite Delivery / Indefinite Quantity contracts within the BARDA Medical Countermeasures (MCM) Clinical Studies Network (CSN).

The below contracts will be modified to include an ordering period of April 1, 2014 – September 30, 2020 (changed).

Icon Government and Public Health Solutions Inc.
Contract no. HHSO100201400001I

Technical Resources International Inc.
Contract no. HHSO100201400002I

PPD Development L.P.
Contract no. HHSO100201400003I

Rho Federal Systems Division, Inc.
Contract no. HHSO100201400004I

The Emmes Company LLC
Contract no. HHSO100201400005I

These contracts provide the clinical planning, clinical execution, and other MCM services that are urgent to the BARDA mission and to the safety and health of the American people. BARDA is in the process of re-competing the MCM CSN contracts and is projecting to make contract awards in the 4th quarter of the Government's Fiscal Year 2020.

Extending the ordering period is needed to prevent a break or lapse in the services provided under these contracts. If the contracts are not extended, BARDA would not be mission ready as it would be unable to readily plan or execute clinical trials for MCMs, chemical, nuclear and radiological threats, pandemic influenza, or emerging diseases.

b. Project background.

The contracts listed above make up BARDA's MCM CSN and were awarded in Fiscal Year 2014 and included a contract minimum of $1,000,000 and maximum is $100,000,000. The ordering periods for the contracts was April 1, 2017 – March 31, 2016.

The Government unilaterally modified the contracts in March 2016 to exercise an option term which extended the ordering period to April 1, 2014 – March 31, 2017.

The Government unilaterally modified the contracts were modified in February 2017 to exercise an option term which extended the ordering period to April 1, 2014 – March 31, 2018.

The Government unilaterally modified the contracts were modified in March 2018 to exercise an option term which extended the ordering period to April 1, 2014 – March 31, 2019.

The Government bilaterally modified the contracts in February 2019 to exercise an option to extend the ordering period to April 1, 2014 – September 30, 2019.

After executing a Justification and Approval for unusual and compelling urgency, the Government bilaterally modified the contracts in September 2019 to extend the ordering period to April 1, 2014 – March 31, 2020.

During the six year ordering period, nine task orders were issued, with at least one task ordering being issued to each of the five contractors for a total of approximately $69.4M obligated.

3. **Description of the supplies or services required to meet the agency's needs (including the estimated value).**

   a. **Project title.**

   Medical Countermeasures Clinical Studies Network

   b. **Project description.**

   The objective of the MCM CSN of contracts is to create a core of contractors to support the planning and execution of clinical studies and other MCM services to support clinical development of product candidates in their development pipeline. Upon issuance of task orders, contractors are to provide clinical services in support of Phase 1, 2, 3, or 4 clinical trials that support the evaluation of Chemical, Biological, Radiological, and Nuclear (CNRN), Pandemic Influenza (PI), and Emerging Infectious Disease (EID) medical countermeasures.

- **Requirement type.**

  ☑ Research & development (R&D)
  ❑ R & D support services
  ❑ Support services (non-R&D)
  ❑ Supplies/equipment
  ❑ Information technology (IT)
  ❑ Construction
  ❑ Architect-engineer (A & E) services
  ❑ Design-build
  ❑ Other (specify): _____

- **Type of action.**

  ❑ New requirement
  ❑ Follow-on
  ☑ Other (specify): Modification to the above listed contracts.

- **Proposed contract/order type.**

  ❑ Firm-fixed-price
  ❑ Other fixed-price (specify, e.g., fixed-price award-fee, fixed-price incentive-fee): _____
  ❑ Cost-plus-fixed-fee
  ❑ Other cost reimbursement (specify, e.g., cost-plus-award-fee, cost-plus-incentive-fee): _____
  ❑ Time and materials
  ☑ Indefinite delivery (specify whether indefinite quantity, definite quantity, or requirements): IDIQ.
  ❑ Other (specify): _____
  ❑ Completion Form ❑ Term form

- **Acquisition identification number.**

  Icon Government and Public Health Solutions Inc.
  Contract no. HHSO100201400001I
  Technical Resources International Inc.
  Contract no. HHSO100201400002I

  PPD Development L.P.
  Contract no. HHSO100201400003I

  Rho Federal Systems Division, Inc.
  Contract no. HHSO100201400004I

  The Emmes Company LLC
  Contract no. HHSO100201400005I

c. Total estimated dollar value and performance/delivery period.

The contract maximums are $100,000,000 and the contract minimums are $1,000,000. The minimums have been satisfied.

A total of $69,418,010.4 has been obligated to the base contract and subsequent task orders; and, if all options are exercised, the total obligated amount would be $71,631,740.13.

The current ordering period is April 1, 2014 – March 31, 2020. BARDA intends to issue contract modifications to extend the ordering periods of the contracts listed above. Upon execution of the modification the new ordering period will be April 1, 2014 – September 30, 2020.

4. Identification of the statutory authority permitting other than full and open competition.

☑ **This acquisition is conducted under the authority of 41 United States Code (U.S.C.) 253(c)(2) as set forth in Federal Acquisition Regulation (FAR) 6.302-2.**

❑ **This acquisition is conducted under the authority of section 4202 of the Clinger-Cohen Act of 1996.**

❑ **This acquisition is conducted under the authority of the Services Acquisition Reform Act of 2003 (41 U.S.C. 428a).**

5. Demonstration that the proposed contractor(s) unique qualifications or the nature of the acquisition requires use of the authority cited.

a. Name and address of the proposed contractor(s).

Icon Government and Public Health Solutions Inc.
1265 Ridge Rd Ste 4
Hinckley, OH 44233-9801

Technical Resources International Inc.
6500 Rock Spring Rd
Bethesda, MD 20817-1197

PPD Development L.P.
929 N Front St
Wilmington, NC 28401-3331

Rho Federal Systems Division, Inc.
6330 Quadrangle Dr Ste 500
Chapel Hill, NC 27517-8079

The Emmes Company LLC
401 N Washington St Ste 700
Rockville, MD 20850-1737

b. Nature of the acquisition and proposed unique qualifications of the contractor(s).

Only the contractors listed above can satisfy BARDA's requirements because they make-up the network of existing contractors. They are the only contractors that possess the operational infrastructure and knowledge required for successful performance. They are also the only contractors capable of providing the required services immediately. Their proposals were evaluated and determined to offer the best value to the Government prior to the award of their Indefinite Delivery / Indefinite Quantity contracts.

6. Description of the efforts made to ensure that offers are solicited from as many potential sources as practicable. Indicate whether a beta.sam.gov notice was or will be publicized as required by FAR Subpart 5.2 and, if not, which exception under FAR 5.202 applies.

BARDA intends to issue modifications to extend contract ordering periods for the Indefinite Delivery / Indefinite Quantity contracts listed above. Offers are not being solicited, and a synopsis is not required nor will be published.

7. Determination by the Contracting Officer that the anticipated cost/price to the Government will be fair and reasonable.

BARDA intends to issue modifications to extend contract ordering periods for the Indefinite Delivery / Indefinite Quantity contracts listed above. No additional funds will be obligated to the contracts with the modifications.

If a task order is awarded under one of the contracts, cost/price will be determined to be reasonable prior to task order award using procedures described in FAR Subpart 15.305 Proposal Evaluation.

8. **Description of the market research conducted (see FAR Part 10) and the results, or a statement of the reasons market research was not conducted.**

   BARDA intends to issue modifications to extend contract ordering periods for the Indefinite Delivery / Indefinite Quantity contracts listed above. Market research was conducted prior to award the contracts, but is not required prior to issuing the modifications to extend the ordering periods.

9. **Any other facts supporting the use of other than full and open competition.**

   It is BARDA's intent to complete negotiations and award new contracts for this requirement as soon as possible, but no later than September 2020. However, the new contracts cannot be awarded earlier than July 2020. A prior six month extension to the ordering period was issued—new ordering period April 1, 2014 – March 31, 2020. Initially, this action was judged to be sufficient to avert any lapse in clinical services. However, the new awards have been unavoidably delayed.

   BARDA oversees the national effort to develop critical MCMs to treat the adverse health effects resulting from exposure to CBRN threat agents, pandemic influenza, and emerging infectious diseases such as the 2019 novel coronavirus (2019-nCoV) as the cause of an outbreak of respiratory illness first detected in Wuhan, China. On January 30, 2020, following the advice of the Emergency Committee, WHO Director-General has declared the outbreak of 2019-nCoV a Public Health Emergency of International Concern. Losing the ability to perform necessary and urgent clinical studies in support of the BARDA mission during a six month gap to awarding the new contracts poses significant risk to the health and safety of the American people.

   In an effort to maintain preparedness, the contract modifications sustain CSN service capabilities for advanced clinical development of MCMs for urgent, time-sensitive or unusual needs. Thus in order to reduce risk to the American people, as a partner program in the National MCM Response Infrastructure, the state of readiness of our response organization needs to be maintained to uphold potential public health and safety requirements. The contract modifications close the gap between the end of the current contracts and the award of contracts for the new solicitation by sustaining urgent and time- sensitive capability for clinical services and maintaining BARDA's readiness to respond to new or emerging biological threats and health emergencies.

10. **Listing of sources, if any, that expressed, in writing, an interest in the acquisition.**

    BARDA intends to issue modifications to extend contract ordering periods for the Indefinite Delivery / Indefinite Quantity contracts listed above. Because this is not a new acquisition, sources were not notified and did not express interest.

11. Statement of the actions, if any, the agency may take to remove or overcome any barriers to competition before any subsequent acquisition for the required supplies or services.

BARDA intends to acquire similar types of services using full and open procedures and has started the acquisition process. On September 6, 2019, BARDA posted three solicitations (75A5011900026; 75A501190002; 775A5011900028) for similar services to the Government Point of Entry. BARDA's anticipates making awards in the 4th quarter of the Government's Fiscal Year 2020.

12. Program office certification.

This is to certify that the portions of this justification that have been developed by the undersigned program office personnel, including supporting information and/or data verifying the Government's minimum needs, schedule requirements and other rationale for other than full and open competition, are accurate and complete.

Official	Name & Title	Signature & Date
Project Officer	Marcy Beth Grace, Ph.D. Contracting Officer's Representative, Clinical Studies Network, Division of Clinical Development	Marcy B. Grace -S Digitally signed by Marcy B. Grace -S Date: 2020.02.24 15:39:25 -05'00'
Project Officer's Immediate Supervisor	Robin Mason, MS MBA Clinical Operations Branch Chief, Division of Clinical Development	Robin M. Mason -S Digitally signed by Robin M. Mason -S Date: 2020.02.24 22:34:26 -05'00'
Head of the Sponsoring Program Office	Robert Walker, MD Director Division of Clinical Development	Robert E. Walker -S Digitally signed by Robert E. Walker -S Date: 2020.02.25 09:03:30 -05'00'

13. Contracting Officer Certification.

This is to certify that the justification for the proposed acquisition has been reviewed and that to the best of my knowledge and belief the information and/or data provided to support the rationale and recommendation for approval is accurate and complete.

Official	Name & Title	Signature & Date
Contracting Officer	Jeffrey Brown, J.D. Contracting Officer, Clinical, Non-Clinical & Regulatory Branch, Division of Contract Management and Acquisition	Jeffrey E. Brown -S Digitally signed by Jeffrey E. Brown -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2001293611, cn=Jeffrey E. Brown -S Date: 2020.02.25 09:21:23 -05'00'