U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUSTIFICATION FOR SOLE SOURCE PROCUREMENT (OPEN MARKET OR GSA) UNDER $250,000

Sole source acquisitions may be used on a limited basis and only when the Contracting Officer's Representative (COR)/Program Official has provided sufficient justification and the Contracting Officer has determined that the circumstances warrant such action. The content for a justification must contain detailed facts and rationale to justify the sole source acquisition. Soliciting from a single source must be done in accordance with FAR 13.106-1(b) or 8.405-6. At a minimum, the following information must be included:

Identification of Program Office, Contracting Activity, and Proposed Requirement, Justification and Program Office Certification:

A. Program Office:

NIOSH/HELD/PPRB
1095 Willowdale Road
Mail Stop: L-2101
Morgantown, WV 26505
Click here to enter text.

B. Contracting Activity:

Centers for Disease Control and Prevention
Office of Financial Resources
Acquisition Branch #5

C. Identification of Requirement:

1. Nature of Action to be Approved by Contracting Officer:

Sole source acquisition of: Research services to evaluate immune responses associated with exposure to engineered stone dust using animal models

a. Procurement Request (PR) Number (if available): Click here to enter text.

2. Proposed Vendor and Estimated Procurement Amount (if available):

a. Proposed Vendor: Dr. Bingyun Li, Department of Orthopaedics, School of Medicine, West Virginia University, Morgantown, WV 26506.

b. Estimated Procurement Amount: [redacted]

3. Is the requirement on GSA Schedule? ☐ Yes ☒ No

If yes, provide schedule number: Click here to enter text.

D. Justification:

1. The justification for this non-competitive action is:

☒ In accordance with FAR 13.106-1(b)(1), "only one source [is] reasonably available" which states that, "For purchases not exceeding the simplified acquisition threshold. (i) Contracting officers may solicit from one source if the contracting officer determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). (ii) Where a single source is identified to provide a portion of a purchase because that portion of the purchase specifies a particular brand-name item, the documentation in paragraph (b)(1)(i) of this section only applies to the portion of the purchase requiring brand-name item. The documentation should state it is covering only the portion of the acquisition which is brand- name."

- ☐ Urgency
- ☐ Exclusive licensing agreements/Proprietary data
- ☐ Brand name required
- ☐ Industrial mobilization
- ☒ Other (e.g., compatibility, space issues, continuity, compatibility, etc.)

☐ In accordance with FAR 8.405-6 "Limiting Sources" which states that, "the only circumstances that may justify the action are – (A) An urgent and compelling need exists, and following the procedures would result in unacceptable delays; (B) Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized; or (C) In the interest of economy and efficiency, the new work is a logical follow-up to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original BPA must not have been previously issued under sole-source or limited-sources procedures."

- ☐ Urgency
- ☐ Only One Source
- ☐ Logical Follow Up
- ☐ Brand name required

2. Other facts supporting sole source procurement:

a. What can this product/service do that other products/services cannot do?
Dr. Li's research at the School of Medicine, West Virginia University (WVU), focuses on nanoparticle toxicity, immunotherapy, nanomedicine, advanced materials, and biomedical engineering. He has been well funded by NIH and other federal agencies and has recently collaborated with NIOSH scientists. This procurement research project aligns closely with his expertise.
The WVU School of Medicine campus is adjacent to the NIOSH Morgantown campus. The vendor's close proximity to the NIOSH campus is a critical operational requirement for this project. The exposure animal studies involve specialized exposure systems that require frequent coordination, monitoring, and, when necessary, immediate technical adjustments. A local vendor enables timely access to the facility, rapid response to operational issues, and efficient coordination with NIOSH staff.

b. What other products/services were considered and why did they not meet the need?
Other potential vendors, including academic institutions and contract research organizations (CROs) with animal study capabilities, were considered. However, these vendors do not meet the combined requirements necessary for this project. Specifically, most alternative vendors are not located in close proximity to the NIOSH Morgantown campus, which is a critical operational requirement for conducting inhalation exposure animal studies.

The specialized nature of these studies requires frequent coordination, real-time monitoring, and immediate technical adjustments of exposure procedures. Vendors located outside the local area would not be able to provide the level of timely access and responsiveness required, resulting in potential delays and increased risk to study quality. Additionally, distance would hinder the prompt transfer and processing of biological samples at NIOSH, which is essential for preserving sample integrity and ensuring reliable results.

Furthermore, while other vendors may have general animal research capabilities, they may lack the specific expertise in nanoparticle toxicity, advanced materials, and animal exposure systems that are directly aligned with the objectives of this project. In contrast, Dr. Li's laboratory at WVU possesses the required technical expertise, established collaboration with NIOSH, and immediate geographic accessibility.

For these reasons, other products/services were considered but do not meet the technical, operational, and logistical requirements of this project.

3. Program Office efforts to seek potential offerors:
The Program Office conducted market research to identify potential offerors capable of performing the required animal exposure studies. This effort included reviewing academic institutions, contract research organizations (CROs), and other research entities with expertise in particulate toxicology, nanoparticle exposure, and animal studies. Publicly available information, institutional websites, and prior collaborations were evaluated to assess technical capabilities, facilities, and relevant experience. In addition, the Program Office considered vendors with demonstrated expertise in pulmonary toxicology, advanced materials, and immunological assessments. Particular attention was given to identifying facilities with the capability to conduct specialized animal exposure studies and handle hazardous emissions.
Through this process, it was determined that while several institutions possess general animal research capabilities, they do not meet the combined requirements of technical expertise, established collaboration with NIOSH, and close geographic proximity to the NIOSH Morgantown campus. Proximity was identified as a critical operational factor necessary to support real-time coordination, equipment oversight, and timely transfer and processing of biological samples.
Based on this market research, West Virginia University (WVU) was identified as the only source that meets all technical, operational, and logistical requirements for this project..

E. Program Office Certification:

I have reviewed this sole source justification and certify the justification is true and accurate to the best of my knowledge and adequate to support other than full and open competition.

CIO Project Officer Name: Yong Qian

CIO Project Officer Signature: Yong Qian

Approval Date: April 8, 2026

Program Management Officer: Yvette Bostic, Management & Program Analyst-HELD

Signature: Yvette F. Bostic -S Digitally signed by Yvette F. Bostic -S Date: 2026.04.29 14:54:05 -04'00'

Approval Date: Click here to enter a date.

Certification Date: Click here to enter a date.

F. Contracting Office Certification:

I have fully relied on the information provided herein and hereby certify that this justification is accurate and complete to the best of my knowledge and belief:

Contracting Officer Name: *Click here to enter text.*

KOURTNEY A. MARSHALL -S Digitally signed by KOURTNEY A. MARSHALL -S Date: 2026.08.11 15:36:34 -04'00'

Contracting Officer Signature:

Certification Date: Click here to enter a date.