Posting Date: July 20, 2021

Closing Date: July 30, 2021 11:30 a.m. ET

Reference Number: 21-045881

To: NCI Bid Board

From: Sharon Coles-Calloway
NCI DCEG Purchasing Agent
coless@mail.nih.gov

Subject: NCI Bid Board Posting - Procurement of services to measure kidney function biomarkers among participants in the Multiethnic Cohort (MEC).

The National Cancer Institute, Occupational and Environmental Epidemiology Branch (OEEB) conducts studies in the United States and abroad to identify and evaluate environmental and workplace exposures that may be associated with cancer risk. OEEB's mission is to combine epidemiology, quantitative exposure assessment, and molecular components into multi-disciplinary studies to provide insight into cancer etiology, chemical carcinogenesis, and mechanisms of action.

In support of the NCI MEC cohort study, the Contractor shall measure levels of creatinine and cystatin C in serum samples from selected participants in the MEC. The Contractor shall confirm the specifications for serum samples to be delivered (e.g., volume requirements, vial type, labeling/barcoding) and coordinate with NCI personnel for all aspects of delivery and performance. The vendor shall also prepare a template of the Excel file that will be used to report assay results, document the receipt of all serum samples in a MS Excel file with the unique ID of each sample, perform assays measuring serum levels of creatinine and cystatin C for each sample submitted. In addition, the vendor shall record assay results, test date, batching information, and quality control data (if applicable) in the Excel file and lastly, the vendor shall provide the NCI Contracting Officer's Representative (COR) with a copy of the Excel data file upon completion

The National Cancer Institute plans to procure services to measure kidney function biomarkers among participants in the Multiethnic Cohort (MEC). However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must contain information and material in sufficient detail to allow NCI to determine is the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on July 30, 2021 ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Sole Source Justification:

The laboratory at Canary Biosciences LLC conducted the measurements of serum creatinine and cystatin C for our prior investigation of serum PFAS concentrations and RCC risk in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial (Shearer et al, JNCI 2021; 2 PMCID: PMC8096365). The laboratory has also measured these same markers as part of another ongoing investigation within our branch (contract # 75N91020P00729). To ensure scientific comparability across studies, the same laboratory technique and group is highly desirable to eliminate any lab to lab variation. Furthermore,

utilizing a single source for serum measurements of these kidney function markers minimizes the sample volume requirements and eliminates additional shipping and processing costs.

Attached Documents:
SF18
Statement of Work
FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (AUG 2019) is applicable and available in full text upon request
FAR Clause 52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment

Released 08/05/99. Submitted to but not yet approved by NIH Forms Officer.

REQUEST FOR QUOTATION
(THIS IS NOT AN ORDER)

THIS RFQ [X] IS [ ] IS NOT A SMALL BUSINESS SET-ASIDE

PAGE 1 OF PAGES 1

1. REQUEST NO.	2. DATE ISSUED	3. REQUISITION/PURCHASE REQUEST NO.	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING
	07/20/2021	21-045881		

5a. ISSUED BY	6. DELIVER BY *(Date)*
NIH/NCI-CCR P-ARC	12 months from receipt of order

5b. FOR INFORMATION CALL *(NO COLLECT CALLS)*

NAME	TELEPHONE NUMBER		7. DELIVERY	
	AREA CODE	NUMBER	[X] FOB DESTINATION	[ ] OTHER *(See Schedule)*
Sharon Coles-Calloway, Purchasing Agent	240	276-7348	9. DESTINATION	

8. TO:			
a. NAME	b. COMPANY		a. NAME OF CONSIGNEE
c. STREET ADDRESS			b. STREET ADDRESS
d.. CITY	e.. STATE	f.. ZIP CODE	c. CITY
			d.. STATE / e. ZIP CODE

10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS *(Date)*

7/30/2021 11:30 ET

IMPORTANT: This is a request for information, and quotations furnished are not offers. If you are unable to quote, please indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or services. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotations must be completed by the quoter.

11. SCHEDULE *(Include applicable Federal, State and local taxes)*

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
001	Procurement of services to measure kidney function biomarkers among participants in the Multiethnic Cohort (MEC) Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to Sharon Coles-Calloway at coless@mail.nih.gov See attached statement of need. This will be awarded as a Firm-Fixed Price Contract.	1	ea	$_____	$_____

12. DISCOUNT FOR PROMPT PAYMENT	a. 10 CALENDAR DAYS (%)	b. 20 CALENDAR DAYS (%)	c. 30 CALENDAR DAYS (%)	d.. CALENDAR DAYS NUMBER	d.. CALENDAR DAYS PERCENTAGE

NOTE: Additional provisions and representations [ ] are [ ] are not attached.

13. NAME AND ADDRESS OF QUOTER	14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION	15. DATE OF QUOTATION
a. NAME OF QUOTER		
b. STREET ADDRESS	16. SIGNER	
c. COUNTY	a. NAME *(Type or print)*	b. TELEPHONE AREA CODE
d. CITY / **e. STATE** / **f. ZIP CODE**	c. TITLE *(Type or print)*	NUMBER

STATEMENT OF WORK (SOW)

1.0 TITLE

Procurement of services to measure kidney function biomarkers among participants in the Multiethnic Cohort (MEC)

2.0 BACKGROUND

The Multiethnic Cohort (MEC) is a large and diverse prospective cohort study consisting of more than 215,000 men and women aged 45-75 years at baseline (1993-1996) from different racial/ethnic groups (African Americans, 16% of participants; Japanese Americans, 26%; Latinos, 22%; Native Hawaiians, 6%; and whites, 23%) living in Hawaii and California. The prospective MEC biospecimen sub-cohort was established from 2001 to 2006 by asking surviving cohort members to provide specimens of blood and urine.

Per- and polyfluoroalkyl substances (PFAS) are man-made chemicals that have been used to make firefighting foams, non-stick cookware coating, and other commercial products since the 1950's. Perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and other PFAS were detectable in sera from >98% of the general U.S. population, and levels of several PFAS differed by race/ethnicity. In 2017, the International Agency for Research on Cancer (IARC) classified PFOA, the most well-studied PFAS, as a possible human carcinogen (Group 2B) based in part on limited epidemiologic evidence of associations with kidney cancer. Notably, in our prospective investigation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, we observed positive associations with risk of renal cell carcinoma (RCC), the most common form of kidney cancer, for serum concentrations of PFOA, PFOS and perfluorohexane sulfonic acid (PFHxS) at levels comparable to those seen in the general population. These associations persisted after adjustment for estimated glomerular filtration rate (eGFR), which was calculated using the chronic kidney disease epidemiology collaboration (CKD-EPI) equation based on measured serum levels of creatinine and cystatin C. There is an important need to replicate findings of pre-diagnostic serum PFAS concentrations and RCC risk in general population studies with greater racial/ethnic diversity than exists in PLCO.

We plan to conduct a nested case-control study of serum PFAS levels and RCC risk within the Multiethnic Cohort (MEC). To account for the potential effects of kidney function on serum PFAS concentrations among the MEC participants that will be included in this investigation, we plan to measure serum levels of kidney function biomarkers (creatinine and cystatin C). Similar to our previous investigation in PLCO, these kidney function markers will be used to calculate eGFR for each of the selected cases and controls.

2.1 OBJECTIVE

STATEMENT OF WORK (SOW)

The primary objective is to measure serum markers of kidney function (creatinine and cystatin C) as part of a nested case-control study of serum PFAS levels and renal cell carcinoma (RCC) risk within the MEC.

3.0 SCOPE

The Contractor shall measure levels of creatinine and cystatin C in serum samples from selected participants in the MEC.

4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS

The Contractor shall perform the following tasks:

1. Confirm the specifications for serum samples to be delivered (e.g., volume requirements, vial type, labeling/barcoding) and coordinate with NCI personnel for all aspects of delivery and performance.
2. Prepare a template of the Excel file that will be used to report assay results.
3. Document the receipt of all serum samples in a MS Excel file with the unique ID of each sample.

4. Perform assays measuring serum levels of creatinine and cystatin C for each sample submitted.
5. Record assay results, test date, batching information, and quality control data (if applicable) in the Excel file
6. Provide the NCI Contracting Officer's Representative (COR) with a copy of the Excel data file upon completion.

5.0 GOVERNMENT RESPONSIBILITIES

The Government technical point of contact (TPOC) will coordinate with the Contractor to deliver samples to the Contractor's facilities. The Government will be responsible for arranging shipment of samples to and from the Contractor.

Risk of loss or damage to the samples provided under this task order shall remain with the Government until samples have been delivered to the Contractor.

6.0 TYPE OF ORDER

This is a firm fixed price purchase order for non-severable services.

7.0 PERIOD OF PERFORMANCE

The period of performance shall be for 12-months from date of award.

STATEMENT OF WORK (SOW)

8.0 PLACE OF PERFORMANCE

Services shall be provided at the Contractor's facilities, the facilities of its sub-contractors, and/or facilities authorized by the Contractor.

8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

All deliverables shall be per the following deliverable schedule:

DELIVERABLE NO.	DELIVERABLE DESCRIPTION	FORMAT REQUIREMENTS	DUE DATE
1	Confirm sample specifications and coordinate with NCI personnel	Confirmation of specifications via e-mail to the NCI COR and teleconference for coordination	10 days after award
2	Template of file for reporting assay results	Microsoft Excel file submitted via e-mail to the NCI COR	30 days after award
3	Receipt of all serum samples with the unique ID of each sample.	Microsoft Excel file submitted via e-mail to the NCI COR upon completion.	10-days after receipt of samples
4	Serum creatinine and cystatin C measurements	Microsoft Excel file submitted via e-mail to the NCI COR upon completion.	15-days prior to expiration of the period of performance

9.0 PAYMENT TERMS

Payment shall be made upon delivery and acceptance of all deliverables.

The NCI will not accept invoices which include items not listed on the Offeror's initial proposal and incorporated into the schedule of items for the resulting award. Payment authorization requires submission and approval of invoices to the TPOC and NIH OFM, in accordance with the attached payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: PROMPT PAYMENT (JAN 2017) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

9.1 INVOICE REQUIREMENTS

A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor.

1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
2. Remit-to address (Name and complete mailing address to send payment).
3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on the invoice.
4. Invoice date.
5. Unique invoice #s for all invoices per vendor regardless of site.
6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
7. Data Universal Numbering System (DUNS) or DUNS + 4 as registered in the SAM.gov.
8. Federal Taxpayer Identification Number (TIN). In those exceptional cases where a contractor does not have a DUNS number or TIN, a Vendor Identification Number (VIN) must be referenced on the invoice. The VIN is the number that appears after the contractor’s name on the face page of the award document.
9. Identify that payment is to be made using a three-way match.
10. Description of supplies/services that match the description on the award, by line billed.*
11. Freight or delivery charge must be billed as shown on the award. If it is included in the item price do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or services performed, as applicable, and that match the line items specified in the award.*

* NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

B. Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed $100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

C. Mail an original and 1 copy of the itemized invoice to:

National Institutes of Health
Office of Financial Management, Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

For inquiries regarding payment call: (301) 496-6088

In order to facilitate the prompt payment of invoices, it is recommended that the vendor submit a photocopy of the invoice to the “Consignee” designated for the acquisition in blocks 6A – 6E of the face page of the Order/Award document.

9.2 ELECTRONIC INVOICING PROCEDURES

Effective April 1, 2020 all NIH contractors/vendors invoices should be sent electronically via e-mail to the NIH Office of Financial Management (OFM) and the Contracting Officer (CO) using the electronic submission instructions contained in Attachment #2.

This section shall remain in full force and effect until the Government formally notifies the Contractor of a return to mail-in invoice procedures detailed in this award.

9.3 INVOICE PAYMENT

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

9.4 INTEREST PENALTIES

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.
   1. A proper invoice was received by the designated billing office.
   2. A receiving report or other Government documentation authorizing payment was
      processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.
   3. In the case of a final invoice for any balance of funds due the contractor for supplies
      delivered or services performed, the amount was not subject to further settlement
      actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

9.5 PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DEC 2013)

a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment.

As prescribed in 4.2105(a), insert the following provision:

REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (AUG 2019)

(a) Definitions. As used in this provision—

Covered telecommunications equipment or services, Critical technology, and Substantial or essential component have the meanings provided in clause 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

(b) Prohibition. Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Contractors are not prohibited from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(c) Representation. The Offeror represents that—

It [ ] will, [ ] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation.

(d) Disclosures. If the Offeror has responded affirmatively to the representation in paragraph (c) of this provision, the Offeror shall provide the following information as part of the offer—

(1) All covered telecommunications equipment and services offered (include brand; model number, such as original equipment manufacturer (OEM) number, manufacturer part number, or wholesaler number; and item description, as applicable);

(2) Explanation of the proposed use of covered telecommunications equipment and services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b) of this provision;

(3) For services, the entity providing the covered telecommunications services (include entity name, unique entity identifier, and Commercial and Government Entity (CAGE) code, if known); and

(4) For equipment, the entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known).

(End of provision)