Posting Date: January 2, 2025

Closing Date: January 2, 2025, 11:30 a.m. ET

Reference Number: 25-009193

To: NCI Bid Board

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

Subject: NCI Bid Board Posting – fecal sample collection

The National Cancer Institute (NCI) Division of Cancer Epidemiology and Genetics (DCEG) Metabolic Epidemiology Branch (MEB) focuses on high-quality, high impact research to seek to understand the etiology of a number of malignancies and the role of various lifestyle factors and unique exposures. MET's research is predicated on rigorous epidemiologic approaches, with integration of state-of-the-art methods for defining exposures of interest.

The Sister Study is a prospective study of 50,884 women in the US who did not have a personal history of breast cancer at enrollment but had at least one sister previously diagnosed with breast cancer. Recruitment occurred from 2003 to 2009 with biospecimens (i.e., blood, urine, and toenails) collected from >99% of the cohort collected at that time. Within a subset of the Sister Study, the Sisters Changing Lives (SCL) study (N = 2,397), a second round of biospecimens were collected. The assays using the biospecimens from the full cohort and the SCL study have often utilized a case-cohort design with a randomly selected subcohort with oversampling of individuals from underrepresented racial and ethnic groups

MEB plans another pilot study for another round of biospecimen collection is planned within the Sister Study which includes blood and urine samples being. Participants will have the option to provide the blood sample at a collection center or at their home. For the pilot study, 1,000 women who previously provided a second sample (~500 previous breast cancer cases and ~500 women who have not developed breast cancer) will be approached for participation. We assume that approximately 800 women will express interest in the study and be sent the collection supply kits. If we assume a 65% response rate, approximately 520 women will return samples. This pilot study will be able to evaluate the proportion of individuals selecting each collection option and to better determine the participation rates for a supplemental collection aimed to collect samples from a total of 3,000 participants.

The National Cancer Institute plans biospecimen collection coordination with DLH Corporation, Durham, NC. This is not a request for competitive quotation. 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 January 10, 2025, 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 purpose of this procurement is to collect fecal samples in a feasibility study nested within the Sister Study to ascertain the response rates and investigate associations with lifestyle and environmental exposures. The Sister Study has been supported by DLH for the ongoing study procedures and previous biospecimen collections. They store the participant contact information and are the only contractor with permission and access to this essential information to conduct this study.

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
	1/10/2025	25-009193		

5a. ISSUED BY
NIH/NCI-CCR P-ARC

6. DELIVER BY *(Date)*
12 months from receipt of order

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

NAME	TELEPHONE NUMBER	
	AREA CODE	NUMBER
Sharon Coles-Calloway, Purchasing Agent	240	276-7348

7. DELIVERY
[X] FOB DESTINATION [ ] OTHER *(See Schedule)*

9. DESTINATION
a. NAME OF CONSIGNEE

8. TO:

a. NAME	b. COMPANY	b. STREET ADDRESS

c. STREET ADDRESS	c. CITY

d.. CITY	e.. STATE	f.. ZIP CODE	d.. STATE	e. ZIP CODE

10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS *(Date)*
6/26/2020 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	A fecal sample collection to the Sister Study pilot biospecimen collection. 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	
	a. NAME *(Type or print)*	b. TELEPHONE AREA CODE
c. COUNTY		
d. CITY / **e. STATE** / **f. ZIP CODE**	c. TITLE *(Type or print)*	NUMBER

1.0 TITLE

The relationship between the fecal microbiome and cancer: A nested feasibility study within the Sister Study

2.0 BACKGROUND

The Sister Study is a prospective study of 50,884 women in the US who did not have a personal history of breast cancer at enrollment, but had at least one sister previously diagnosed with breast cancer. Recruitment occurred from 2003 to 2009 with biospecimens (i.e., blood, urine, and toenails) collected from >99% of the cohort collected at that time. Within a subset of the Sister Study, the Sisters Changing Lives (SCL) study (N = 2,397), a second round of biospecimens were collected. The assays using the biospecimens from the full cohort and the SCL study have often utilized a case-cohort design with a randomly selected subcohort with oversampling of individuals from underrepresented racial and ethnic groups.

A pilot study for another round of biospecimen collection is planned within the Sister Study which includes blood and urine samples being coordinated by DLH. Participants will have the option to provide the blood sample at a collection center or at their home. For the pilot study, 1,000 women who previously provided a second sample (~500 previous breast cancer cases and ~500 women who have not developed breast cancer) will be approached for participation. We assume that approximately 800 women will express interest in the study and be sent the collection supply kits. If we assume a 65% response rate, approximately 520 women will return samples. This pilot study will be able to evaluate the proportion of individuals selecting each collection option and to better determine the participation rates for a supplemental collection aimed to collect samples from a total of 3,000 participants.

To supplement this pilot study, we will add a fecal sample to be collected at the participant's home using similar methods proposed for the Division of Cancer Epidemiology & Genetics Connect study. For this sample, we will provide the participant with a fecal collection kit with a questionnaire and detailed instructions. The participant will be asked to provide the sample on a fecal occult blood test (FOBT) card to be placed in the provided biohazard bag and shipped to the biorepository for storage.

3.0 OBJECTIVES

The primary objective is to include a fecal sample collection to the Sister Study pilot biospecimen collection.

4.0 SCOPE

The contractor will create a written plan for creating the fecal sample collection kits, distributing these kits, and receiving/storing the kits.

4.1 TECHNICAL REQUIREMENTS

The Contractor shall perform the following task:

1. Create a written plan to outline study procedures.

4.2 PERSONNEL QUALIFICATIONS

Not applicable

4.3 SPECIAL ORDER REQUIREMENTS

Not applicable

5.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

6.0 PERIOD OF PERFORMANCE

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

7.0 PLACE OF PERFORMANCE

Services shall be performed at the Contractor's facility.

8.0 CONTRACTING OFFICERS REPRESENATIVE/TECHNICAL POINT OF CONTACT

All work delivered to the Contracting Officers Representative (COR) *or* Technical Point of Contact (TPOC) will be deemed to have been accepted upon written confirmation of acceptance by the COR/TPOC. The COR/TPOC's approval or revision to the work delivered shall be within the general scope of work for the Purchase Order.

The following individual shall be the COR/TPOC for this task order:

Emily Vogtmann
Metabolic Epidemiology Branch, Division of Cancer Epidemiology & Genetics, NCI, NIH
Email: emily.vogtmann@nih.gov
Phone number: (240) 276-6701
9609 Medical Center Drive
Bethesda, MD 20892

Performance of work under this Purchase Order must be subject to the technical direction of the COR/TPOC identified above. The term "technical direction" includes direction to the Contractor that fills in details and otherwise serves to ensure that tasks outlined in this requirements document are accomplished satisfactorily. Technical direction must be within the scope of this requirements document.

The COR/TPOC **does not have authority** to issue technical direction that:

a. Constitutes a change of assignment or additional work outside of this requirements document
b. Constitutes a change as defined in the clause 52.212-4 (c) governing "Changes";
c. In any manner causes an increase or decrease in the contract price, or the time required for contract performance;
d. Changes any of the terms, conditions, or requirements of the contract;
e. Interferes with the Contractor's right to perform under the terms and conditions of the contract; or
f. Directs, supervises, or otherwise controls the actions of the Contractor's employees.

Technical direction may be oral or in writing. The COR/TPOC shall confirm oral direction in writing within five business days, with a copy to the Contracting Officer. The Contractor shall proceed promptly with performance resulting from the technical direction issued by the COR/TPOC. If, in the opinion of the Contractor, any direction of the COR/TPOC, or their designee, falls within the limitations in (b), above, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government business day.

Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the contract shall be subject to the terms of the clause 52.212-4 (d) titled "Disputes."

9.0 DELIVERABLES SCHEDULE

All written deliverable products shall be submitted in draft format for review, comment and approval by the COR within 11 months of the date of the award. Final copies of approved drafts shall be delivered to the COR within five (5) business days after receipt of the Government's comments.

All written draft and final deliverable products shall be submitted in electronic format for review and comment. If requested, final deliverable products shall be submitted in hard copy; two (2) final bound copies and one (1) unbound flat final copy suitable for reproduction, in addition to an electronic copy. Other quantities and formats may be submitted after prior approval from the COR. Electronic copies shall be submitted in Microsoft Office 2016 (Word, Excel) format or more recent version, or in PDF format, unless prior approval for another format has been obtained from the COR. Deliverables shall be submitted in accordance with the following deliverable schedule:

DELIVERABLE	**DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS**	**DUE DATE**
#1	Written plan in Word or PDF format	11 months after award

10.0 PAYMENT

Payment shall be made 30 days from date of invoice. Payment authorization requires submission and approval of invoices to the COR and NIH OFM, in accordance with the payment provisions/clauses listed in the contract.

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)