

Posting Date: July 9, 2021

Closing Date: July 19, 2021 11:30 a.m. ET

Reference Number: 21-044951

To: NCI Bid Board

From: Sharon Coles-Calloway  
NCI DCEG Purchasing Agent  
[coless@mail.nih.gov](mailto:coless@mail.nih.gov)

Subject: NCI Bid Board Posting - Obtain quantitative mammographic density and clinical data from breast cancer patients in Kenya, Africa

The National Cancer Institute (NCI), Integrative Tumor Epidemiology Branch (ITEB) employs molecular pathology, somatic and germline genomics, and epidemiology to identify environmental and germline risk factors for cancer. The mission of ITEB is to conduct large-scale, international epidemiological research on cancer etiology and progression through integrative analyses of risk factors and tissue profiling to inform prevention and clinical strategies.

In support of the NCI Kenya breast cancer TDLU-MD study, the contractor will collect quantitative MD and clinical data from breast cancer patients included in the ongoing TDLU analysis and with mammograms available. The contractor shall identify and assemble diagnostic mammograms (on both sides whenever possible) from patients included in the TDLU analysis, remove identifiable information from mammograms and generate anonymized image, run Cumulus and density assessment will be performed by a radiologist who had been trained by the group that developed the software. The contractor shall also run a quality control assessment of a masked random sample of 5% of the mammograms within and between batches, selected by the Contractor, shall be carried out to confirm reproducibility of MD measures. In addition, the Contractor shall collect relevant risk factor and clinical information from these patients and share all data (include MD readings) with NCI.

The National Cancer Institute plans to purchase collected quantitative MD and clinical data. 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 if the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on July 19, 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 Aga Khan University Hospital in Nairobi (AKUHN) is uniquely qualified to perform this work because they previously conducted a breast cancer study in which AKUHN collected tissue samples and clinical and epidemiologic data from multiple hospitals across Kenya. The goal of this procurement is to collect mammographic density data from the same set of patients enrolled in the ongoing morphological analysis with morphological features currently being evaluated. No one else has the access to the information on these patients. AKUHN has been a collaborator with multiple PIs in the division and AKUHN's enthusiasm in conducting research, expertise as a pathologist, and their quality of work have been well demonstrated and respected by DCEG collaborators. In summary, AKUHN possesses unique expertise and resources to conduct this study.

Attached Documents:

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

<b>REQUEST FOR QUOTATION (THIS IS NOT AN ORDER)</b>		THIS RFQ <input type="checkbox"/> IS <input type="checkbox"/> IS NOT A SMALL BUSINESS SET-ASIDE		PAGE OF PAGES
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
5a. ISSUED BY			6. DELIVER BY (Date)	
5b. FOR INFORMATION CALL (NO COLLECT CALLS)			7. DELIVERY	
NAME		TELEPHONE NUMBER		<input type="checkbox"/> FOB DESTINATION <input type="checkbox"/> OTHER (See Schedule)
		AREA CODE	NUMBER	9. DESTINATION
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)		<b>IMPORTANT:</b> 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)

<b>12. DISCOUNT FOR PROMPT PAYMENT</b>	a. 10 CALENDAR DAYS (%)	b. 20 CALENDAR DAYS (%)	c. 30 CALENDAR DAYS (%)	d. CALENDAR DAYS
				NUMBER 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
d. CITY		AREA CODE	
e. STATE f. ZIP CODE		c. TITLE (Type or print)	
		NUMBER	

## STATEMENT OF WORK

### 1.0 TITLE

Obtain quantitative mammographic density and clinical data from breast cancer patients in Kenya, Africa

### 2.0. BACKGROUND

General description: Mammographic density (MD) is a radiological representation of stromal and epithelial breast tissue content and extensive MD is a well-established risk factor for breast cancer. Several studies have provided insight into the underlying mechanism of the MD and breast cancer risk association by examining histologic features of breast tissues. Terminal duct lobular unit (TDLU) involution is a histological measure of breast tissue characterized by a reduction in the epithelial component with aging. Less extent of involution, characterized by greater number and size of observed TDLUs, has been associated with higher breast cancer risk among women with benign breast diseases. Previous studies conducted predominantly among white women using diagnostic biopsy specimens for benign breast diseases have demonstrated that reduced TDLU involution was associated with higher MD: women with no or partial involution were more likely to have higher percent MD or dense parenchymal patterns than those with complete involution. This association was subsequently replicated using standardized quantitative measures of TDLU involution. Contrary to these reports, a recent analysis of breast cancer cases within the Multiethnic Cohort, which was highly enriched for women of Japanese ancestry (43%) and included participants who were older (mean age 59.7 years) and thinner than in other studies showed the opposite direction of the association (i.e., greater TDLU involution associated with higher dense area). The explanation of this finding is unresolved but may suggest potential racial variation in the TDLU-MD relationship.

Using data from the Komen Tissue Bank, we recently examined associations between genetic ancestry and TDLU involution among 1,996 healthy women. Compared with women of European ancestry, women of African ancestry showed significantly delayed TDLU involution. Given the association of delayed TDLU involution with TNBC, our findings suggest that age-related TDLU involution may at least in part mediate breast cancer risk associated with African ancestry and provide a mechanistic clue to the higher risk of developing TNBC among Black American women.

How the requirement evolved: In collaboration with Dr. Shahin Sayed at Aga Khan University Hospital in Nairobi (AKUHN), we recently developed a breast cancer study with the goal of investigating TDLU involution in relation to breast cancer subtypes and risk factors in Kenya. We have conducted visual assessment of TDLUs on H&E stained images on adjacent normal tissue from 240 Kenya breast cancer patients. We are currently developing an AI-based approach to perform automated quantitative TDLU analyses on this set of patients. Among these patients, diagnosis mammograms are available for ~200 patients. We plan to obtain quantitative mammographic density data from these patients to assess TDLU-MD relationship in this unique African breast cancer population.

## **2.1. OBJECTIVE**

Project Objectives: The specific aim for this procurement is to assemble mammograms and obtain quantitative MD measurement using Cumulus, software for density assessment (Sunnybrook Health Sciences Centre, Toronto, ON, Canada). In addition, relevant patient risk factor and clinical data will be collected from this set of patients.

## **3.0. SCOPE**

In support of the NCI Kenya breast cancer TDLU-MD study, AKUHN will collect quantitative MD and clinical data from breast cancer patients included in the ongoing TDLU analysis and with mammograms available.

## **4.0. CONTRACT REQUIREMENTS/AND PERSONNEL QUALIFICATIONS (IF APPLICABLE)**

The contractor shall:

- 4.1 Identify and assemble diagnostic mammograms (on both sides whenever possible) from patients included in the TDLU analysis.
- 4.2 Remove identifiable information from mammograms and generate anonymized images.
- 4.3 Run Cumulus and density assessment will be performed by a radiologist who had been trained by the group that developed the software.
- 4.4 A quality control assessment of a masked random sample of 5% of the mammograms within and between batches, selected by the Contractor, shall be carried out to confirm reproducibility of MD measures.
- 4.5 Collect relevant risk factor and clinical information from these patients and share all data (include MD readings) with NCI.

## **5.0. TYPE OF ORDER**

This is a firm fixed price purchase order.

## **6.0. PERIOD OF PERFORMANCE**

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

## **7.0. PLACE OF PERFORMANCE**

Shahin Sayed

Aga Khan University Hospital in Nairobi  
 3<sup>rd</sup> Parklands Avenue, Off Limuru Road  
 P.O Box 30270  
 GPO 00100, Nairobi, Kenya  
 Phone (Off): +254203662234  
 Phone (Mobile): +254733719045  
 Email: [shaheen.sayed@aku.edu](mailto:shaheen.sayed@aku.edu)

## 8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

<i>DELIVERABLE</i>	<i>DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS</i>	<i>DUE DATE</i>
4.1	Identify and assembly mammograms	Sept 30 <sup>st</sup> , 2021
4.2	Generate anonymous images	Dec 31 <sup>st</sup> , 2021
4.3 and 4.4	MD measurements and QC	March 31 <sup>st</sup> , 2022
4.5	Collect and share data with NCI.	April 30, 2022

## 9.0 PAYMENT

Payment shall be made in 1 payment. Payment authorization requires submission and approval of invoices to the COR 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 (JUL 2013) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

### I 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 Central Contractor Registration (CCR).
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.

## II. 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.

## III. 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.

## IV. 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)