

Posting Date: June 11, 2021

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

Reference Number: 21-039410

To: NCI Bid Board

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

Subject: Molecular and immune landscape and etiology of acral lentiginous melanoma – Spanish centers

The National Cancer Institute, 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 acral melanoma study, the vendor shall perform digital scanning of tumor tissue collected by participating Spanish centers; the scan shall be uploaded to the password-protected website HaloLink for centralized pathology review. The vendor shall also extract DNA and RNA from tumor and normal tissue samples collected by these centers; the extracted DNA samples shall be sent to Dr. David Adams at the Wellcome Sanger Institute for further sequencing and array analyses and the RNA samples to the NCI for RNA sequencing analysis.

The National Cancer Institute plans to collect pathology images and formalin-fixed paraffin-embedded (FFPE) tissue blocks and extract DNA and RNA in acral lentiginous melanoma (ALM) patients from all participating Spanish centers (i.e., in Barcelona, Madrid, and Valencia). This work will include the assembling and sectioning of FFPE tumor and normal tissue blocks, digital scanning of the hematoxylin- and eosin-stained (H&E) slides from the tumor sections, and extraction of DNA and RNA from tumor and normal tissue. 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 June 21, 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 current study needs to collect a large number of ALM, which is a very rare condition. NCI has successfully conducted a series of cutaneous melanoma studies with a network of research centers in Mediterranean countries. Last year, leveraging this network, we have assembled 150 ALM cases among Italian, Croatian, and Greek centers in this network. We now plan to expand this study to Spanish centers in the network, assembling another 200 already existing cases using the same approach to increase sample size and population

representation in the Mediterranean.

The Asociación para la Prevención y la Investigación del Melanoma Cutáneo led by Dr. Eduardo Nagore has established working relationships to provide pathology and laboratory services to the Spanish research centers, and it was identified by the research centers as the best team for performing the tasks outlined in this contract. Assembling and processing biospecimens in the country where they were collected also reduce logistic and administrative hurdles. Dr. Nagore is an internationally renowned dermatologist and expert in melanoma genetic research; he has more than 300 publications in his area of expertise

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

REQUEST FOR QUOTATION (THIS IS NOT AN ORDER)		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 OF CONSIGNEE	
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)		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)

12. DISCOUNT FOR PROMPT PAYMENT	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 (SOW)

STATEMENT OF WORK

1.0 TITLE

Molecular and immune landscape and etiology of acral lentiginous melanoma – Spanish centers

2.0 BACKGROUND

Acral lentiginous melanoma (ALM) is a rare subtype of melanoma associated with poor survival. Unlike other cutaneous melanoma subtypes, ALM has not been linked to sun exposure, and much of its risk factors and exposures remain unknown. The clinical, pathological, and genomic characteristics of ALM are also distinct from sun-exposed melanomas. To better understand the etiology, prevention, and treatment of ALM, studies that comprehensively characterize the genomic, transcriptomic, and immune landscape of ALM are needed. So far, such studies have been limited by small sample sizes (n = 1–122); some had a limited number of genes tested, and many did not have both DNA and RNA sequencing data. In addition, Mediterranean populations are also under-represented in melanoma research in general.

NCI has conducted a series of studies on the molecular characteristics of cutaneous melanoma collected by a network of research centers in countries across the Mediterranean. In the past year, leveraging this network, NCI has directed a study of ALM among Italian, Croatian and Greek centers, which collected clinical and epidemiologic data, pathology images, and biospecimens, and extracted DNA and RNA for whole-exome sequencing (WES) and RNA sequencing for 150 cases. We now plan to expand this study to Spanish centers in the network, using the same approach to increase sample size and population representation in the Mediterranean.

2.1 OBJECTIVE

The purpose of this procurement is to fund the collection of pathology images and formalin-fixed paraffin-embedded (FFPE) tissue blocks and the extraction of DNA and RNA in ALM patients from all participating Spanish centers (i.e., in Barcelona, Madrid, and Valencia). This work will include the assembling and sectioning of FFPE tumor and normal tissue blocks, digital scanning of the hematoxylin- and eosin-stained (H&E) slides from the tumor sections, and extraction of DNA and RNA from tumor and normal tissue.

3.0 SCOPE

In support of the NCI acral melanoma study, the vendor shall perform digital scanning of tumor tissue collected by participating Spanish centers; the scan shall be uploaded to the password-protected website HaloLink for centralized pathology review. The vendor shall also extract DNA and RNA from tumor and normal tissue samples collected by these centers; the extracted DNA samples shall be sent to Dr. David Adams at the Wellcome Sanger Institute for further sequencing and array analyses and the RNA samples to the NCI for RNA sequencing analysis.

4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS

The contractor shall:

STATEMENT OF WORK (SOW)

- 4.1 Assemble tumor and normal FFPE tissue blocks of ALM patients from all participating Spanish centers (i.e., in Barcelona, Madrid, and Valencia). It is estimated that the collection will include 200 subjects with corresponding 400 FFPE tissue blocks (tumor and normal).
- 4.2 Section 20 slides of 10 µm from each of 400 FFPE tissue blocks. Prepare H&E slides from the sections. Scan the H&E slides digitally and upload the image into the password-protected website HaloLink for a centralized pathology review.
- 4.3 Extract DNA and RNA from 400 tumor and normal tissue sections following the Wellcome Sanger Institute protocol. Ship the extracted DNA to the Wellcome Sanger Institute and the RNA samples to the National Cancer Institute.
- 4.4 Provide a monthly report on the progress of the activities to the NCI Technical Point of Contact via email.
- 4.5 It is expected that the laboratory will exercise the above-listed requirements for 100 tissue blocks every three months for a total of 400 blocks.

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 a one 12-month base period starting from the approval of the contract, with two 12-month option periods.

7.0 PLACE OF PERFORMANCE

Asociación para la Prevención y la Investigación del Melanoma Cutáneo
C/o Dr. Eduardo Nagore
Avenida Baron De Carcer, 42-17, Valencia, Spain, 46001
Phone: 0034-660425852
Email: eduardo.nagore.e@gmail.com

8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

<i>DELIVERABLE</i>	<i>DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS</i>	<i>DUE DATE</i>
4.1	Assemble a total of 100 tumor and normal FFPE tissue blocks from 50 ALM patients from all participating Spanish centers.	Every 3 months
4.2	For 100 FFPE tissue blocks, section 20 slides of 10 µm from each block, prepare H&E slides from the sections, scan the H&E slides digitally and upload the image into the password-protected website HaloLink for centralized pathology review.	Every 3 months

STATEMENT OF WORK (SOW)

4.3	Extract DNA and RNA from tissue sections of 100 blocks following the Wellcome Sanger Institute protocol. Ship the extracted DNA samples to the Wellcome Sanger Institute and RNA samples to the NCI	Every 3 months
4.4	Provide a monthly report on the progress of the activities to the NCI Technical Point of Contact via email	Every month

9.0 PAYMENT

Payment shall be made in 4 payments. 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)

STATEMENT OF WORK (SOW)

- 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.

STATEMENT OF WORK (SOW)

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)