

Posting Date: April 30 2024

Closing Date: May 9, 2024 11:30 a.m. ET

Reference Number: 24-029685

To: NCI Bid Board

From: Viviane Rivera  
NCI CCR P-ARC  
[Viviane.rivera@nih.gov](mailto:Viviane.rivera@nih.gov)

Subject: NCI Bid Board Posting – Antibody engineering with DNA for The Molecular Imaging Program (MIP)

At the National Cancer Institute (NCI), The Molecular Imaging Program (MIP) mission is to advance cancer therapies using molecular imaging. The MIB conducts research in designing, developing and testing new novel targeted imaging agents for the detection and characterization of cancer. These imaging agents include tissue-specific MRI, PET, radionuclide, and optical probes. We are focused on the clinical translation of targeted imaging agents for cancer imaging.

The primary objective of this purchase is to buy the engineered antibody with DNA testing that will be used for in vivo imaging studies targeting breast cancer . These studies will be done by laboratory staff in the Molecular Imaging Program (MIP) laboratory.

The National Cancer Institute plans to purchase the Antibody engineering with DNA from Creative Biolabs Inc, to perform this work. 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 May 9, 2024, 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:

Creative Biolabs is well-equipped with the knowledge, technologies, and resources required to handle the complexities of these two specialized areas in the project. Previous work with Creative Biolabs has always been successful and they were able to generate novel antibodies and their fragments, that other suppliers failed.

Attached Documents:

SF18

Statement of Work

FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (JAN 2014) is applicable and available in full text upon request

<b>REQUEST FOR QUOTATION</b> <i>(THIS IS NOT AN ORDER)</i>		THIS RFQ <input checked="" type="checkbox"/> IS <input type="checkbox"/> IS NOT A SMALL BUSINESS SET-ASIDE		PAGE OF PAGES 1 1	
1. REQUEST NUMBER <b>24-029685</b>	2. DATE ISSUED <b>04/30/2024</b>	3. REQUISITION/PURCHASE REQUEST NUMBER <b>24-029685</b>	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING	
5a. ISSUED BY			6. DELIVER BY (Date) <b>06/29/2024</b>		
5b. FOR INFORMATION CALL (NO COLLECT CALLS)			7. DELIVERY		
NAME <b>Viviane Rivera</b>		TELEPHONE NUMBER		<input checked="" type="checkbox"/> FOB DESTINATION <input type="checkbox"/> OTHER (See Schedule)	
		AREA CODE <b>240</b>	NUMBER <b>760-7125</b>	9. DESTINATION	
8. TO:			a. NAME OF CONSIGNEE <b>Orit JACOBSON 240-858-7517</b>		
a. NAME		b. COMPANY		b. STREET ADDRESS <b>9000 Rockville Pike Bldg 10 RM 1B55</b>	
c. STREET ADDRESS			c. CITY <b>Bethesda</b>		
d. CITY		e. STATE	f. ZIP CODE	d. STATE <b>MD</b>	e. ZIP CODE <b>20892</b>
10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS (Date) <b>05/09/2024</b>		IMPORTANT: This is a request for information and quotations furnished are not offers. If you are unable to quote, please so 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 service. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotation must be completed by the quoter.			
<b>11. SCHEDULE (Include applicable Federal, State and local taxes)</b>					
ITEM NUMBER (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
001	Item: Antibody ssDNA conjugation • ssDNA modified with 5' Azide by CBL (5mg required) • Pertuzumab Antibody modified with DBCO provided by CBL (30 mg required) • Conjugation Service  Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to: Viviane Rivera at <a href="mailto:viviane.rivera@nih.gov">viviane.rivera@nih.gov</a>  See attached statement of need This will be awarded as a Firm-Fixed Price Contract	1	ea	0.00	\$0.00
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 <input type="checkbox"/> are <input type="checkbox"/> 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)

Instructions: This document should be used for the acquisition of SERVICES. Instructions (and sample language) for completion are in red, and should be excluded from the completed document.

### 1.0 TITLE

Synthesis of engineered antibody-DNA construct and its double-stranded DNA.

### 2.0 BACKGROUND

The NCI, CCR, Molecular Imaging Branch (MIB) is requesting a contractor to perform custom synthesis of one novel antibody engineered with ssDNA. The MIB is currently engaged in the advancement of tracer's development for cancer imaging and radiotherapy. To allow controlled PK of antibody in vivo, while targeting specific receptors expressed by tumors, we design the following engineered antibody construct.

### 2.1 OBJECTIVE

The primary objective of this project is to synthesize an engineered antibody-DNA construct, which will target HER2 and enable us to control the long half-life of antibody tracers in vivo.

### 3.0 SCOPE

The contractor shall provide all labor, material, and equipment necessary to perform the custom synthesis.

Contractor will take about 6-8 weeks from date of award to generate the engineered antibody.

The Government shall not exercise any supervision or control over the contract service providers performing the services herein. Such contract service providers shall be accountable solely to the Contractor who, in turn is responsible to the Government. Contractor shall provide all personnel, labor, facilities, materials and equipment necessary to generate the synthesized compounds. All development and production will be performed off-site.

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

Contractor shall have experience in performing synthesis of engineered antibodies.

## STATEMENT OF WORK (SOW)

### 5.0 TYPE OF ORDER

This is a firm fixed price purchase order.

### 6.0 PERIOD OF PERFORMANCE

The period of performance will be about 6-8 business weeks from date of award.

### 7.0 PLACE OF PERFORMANCE

Creative Biolabs Inc. 45-1 Ramsey Road, Shirley, NY 11967, USA

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

Deliverables: Antibody ssDNA conjugation

Deliverable The standard QC includes the characterization of ADCs by Mass Spectrometry as below:

- SEC for aggregation (Agg%)
- HIC for unconjugated antibody (UmAb%)
- LC-MS or HIC for DAR
- Endotoxin

Delivery time: About 6-8 business weeks from date of award

### 9.0 PAYMENT

Payment shall be made with a purchase order according to the testing need by the lab. 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 considered in the computation of any interest penalty owed the Contractor.

## STATEMENT OF WORK (SOW)

1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephonenumber, 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: ContractNumber; 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. Unique Entity Identifier (UEI) which is in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number.
8. Federal Taxpayer Identification Number (TIN). In those rare cases where a contractor does not have a UEI 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.

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.

B. The Contractor shall submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at <https://www.ipp.gov> with a copy to the approving official, as directed below.

The Contractor shall submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer's Representative:

## STATEMENT OF WORK (SOW)

Approving Official: Contracting Officer  
Name- Email Address-

Contracting Officer's Representative  
Name- Email Address-

### 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 (November 2021)

(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.

## STATEMENT OF WORK (SOW)

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial products or commercial services.

(End of Clause)

### **V. HHSAR 352.232-71 Electronic Submission of Payment Requests (February 2, 2022)**

(a) Definitions. As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at [www.ipp.gov](http://www.ipp.gov) or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer’s written authorization with each payment request.

(End of Clause)