

Posting Date:	March 5, 2024
Closing Date:	March 15, 2024, 11:30 a.m. ET
Reference Number:	24-020169
To:	NCI Bid Board
From:	Tanika Graves
	NCI CCR Procurement, Contract Specialist gravesta@nih.gov

Subject: NCI Bid Board Posting - Production of Monoclonal Antibody to sTF

The Laboratory of Immune Cell Biology is composed of independent laboratories with a common interest in the biology of the immune system at the molecular and cellular levels.

The Liu Lab as a part of Laboratory of Immune Cell Biology has a requirement for a custom rabbit monoclonal antibody specific to the soluble human tissue factor that can detect soluble tissue factor in blood can be a diagnostic marker of early/ongoing thrombosis/clotting.

The NCI plans to purchase this service request from GeneScript USA, Inc. Piscataway, NJ to perform this work. This is not a request for a 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 March 15, 2024 ET. A determination by the Government not to compete with this requirement based upon responses to this notice is solely within its discretion. Information received will be considered exclusively to determine whether to conduct a competitive procurement.

Sole Source Justification:

GenScript's OptimumGene[™] Gene Design system is a proprietary PSO-based gene optimization technology that can alter both naturally occurring and recombinant gene sequences to achieve the highest possible levels of productivity in any given expression system. GenScript has accumulated years of experience in codon optimization and gene synthesis. Our system has optimized over 50,000 gene sequences in almost all major expression systems.

Attached Documents:

SF18 Statement of Work FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (JULY 2021) is applicable and available in full text upon request.

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1.0 TITLE

Custom Rabbit Monoclonal Antibodies-Human Soluble Tissue Factor

2.0 BACKGROUND

Our research findings revealed a critical function of the protein Tissue Factor, and demonstrated that the soluble Tissue Factor, not the membrane bound full length Tissue Factor, mediates hypercoagulation under pathological conditions. Also, our findings provided potential therapies for treating sepsis or viral infection-caused thrombosis by targeting soluble Tissue Factor. The sTF is a novel diagnosis marker and could be detected in the early stage of thrombosis. Currently there is no commercial antibody that can specifically detect soluble Tissue Factor but not the membrane non-functioning Tissue Factor. By developing this monoclonal antibody specific to the soluble human tissue factor that can detect soluble tissue factor in blood can be a diagnostic marker of early/ongoing thrombosis/clotting.

3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

The Liu Lab as a part of Laboratory of Immune Cell Biology has a requirement for a custom rabbit monoclonal antibody specific to the soluble human tissue factor that can detect soluble tissue factor in blood can be a diagnostic marker of early/ongoing thrombosis/clotting. Contractor to provide all labor, materials and equipment to produce a Rabbit Monoclonal Antibody specific for Soluble Tissue Factor for the government.

The following product features/characteristics are required for this requirement:

Key features

High Density (HD) Transient Expression service for the high-titer production of your recombinant antibodies and proteins in either CHO or HEK293 cells. Using HD mammalian cell culture, this HD Transient Expression service can deliver unprecedented improvements in functional protein/rAb yields compared to regular Transient Expression services. HD-HEK and HD-CHO for choice of HEK293 or CHO expression

- Combo expression evaluation to compare regular and HD transient expression
- Alternative approach for difficult and low-yield proteins
- Yield improvements ranging up to 100 fold
- Shortened turnaround time (sequence to protein/antibody in as little as 10 weeks)
- Up to 3g/L rAb titer possible

4.2 DELIVERY / INSTALLATION

The final monoclonal rabbit Antibody against human soluble Tissue Factor will be delivered to: Zhenggang Liu/Swati Choksi National Institutes of Health (NIH) - Bethesda Room 1130 Building 37, 37 Convent Dr Bethesda, MD 20892, United States choksis@mail.nih.gov VAT No:ATU57469858

All Antibody products will be delivered with 179 day turnaround. However, *Turnaround Time may vary depending on the size and complexity of the project. The Estimated Turnaround Time includes the production time of template plasmids if applicable, and does not include delays incurring due to waiting time for customer-provided material, project communication after order confirmation, or "pause/hold" request by customer.

4.3 TRAINING

No Training is needed for this product.

5.0 PAYMENT

Payment shall be made <u>(Payment authorization requires submission and approval of invoices to the</u> COR and NIH OFM, in accordance with the 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.

TERMS AND CONDITIONS-SIMPLIFIED ACQUISITIONS (OTHER THAN COMMERCIAL ITEMS) (JUL 2021), FAR 52.213-4

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses that are incorporated by reference:

(1) The clauses listed below implement provisions of law or Executive order:

(i) <u>52.203-19</u>, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(ii) <u>52.204-23</u>, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(iii) <u>52.204-25</u>, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(iv) <u>52.222-3</u>, Convict Labor (JUN 2003) (E.O.11755).

(v) <u>52.222-21</u>, Prohibition of Segregated Facilities (APR 2015).

(vi) <u>52.222-26</u>, Equal Opportunity (SEP 2016) (E.O.11246).

(vii) <u>52.225-13</u>, Restrictions on Certain Foreign Purchases (FEB 2021) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

(viii) <u>52.233-3</u>, Protest After Award (AUG 1996) (<u>31 U.S.C.3553</u>).

(ix) <u>52.233-4</u>, Applicable Law for Breach of Contract Claim (OCT 2004) (Pub.L.108-77, 108-78 (<u>19 U.S.C. 3805 note</u>)).

(2) Listed below are additional clauses that apply:

(i) <u>52.232-1</u>, Payments (APR 1984).

(ii) <u>52.232-8</u>, Discounts for Prompt Payment (FEB 2002).

(iii) <u>52.232-11</u>, Extras (APR 1984).

(iv) <u>52.232-25</u>, Prompt Payment (JAN 2017).

(v) <u>52.232-39</u>, Unenforceability of Unauthorized Obligations (JUN 2013).

(vi) <u>52.232-40</u>, Providing Accelerated Payments to Small Business Subcontractors (DEC 2013).

(vii) <u>52.233-1</u>, Disputes (MAY 2014).

(viii) <u>52.244-6</u>, Subcontracts for Commercial Items (JUL 2021).

(ix) <u>52.253-1</u>, Computer Generated Forms (JAN 1991).

(b) The Contractor shall comply with the following FAR clauses, incorporated by reference, unless the circumstances do not apply:

(1) The clauses listed below implement provisions of law or Executive order:

(i) <u>52.204-10</u>, Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020)(Pub. L. 109-282) (<u>31 U.S.C. 6101 note</u>) (Applies to contracts valued at or above the threshold specified in FAR <u>4.1403</u>(a) on the date of award of this contract).

(ii) 52.222-19, Child Labor-Cooperation with Authorities and Remedies (JAN 2020) (E.O. 13126) (Applies to contracts for supplies exceeding the micropurchase threshold, as defined in FAR 2.101 on the date of award of this contract).

(iii) <u>52.222-20</u>, Contracts for Materials, Supplies, Articles, and Equipment., Contracts for Materials, Supplies, Articles, and Equipment (JUN 2020) (<u>41 U.S.C.chapter 65</u>) (Applies to supply contracts over the threshold specified in FAR 22.602 on the date of award of this contract, in the United States, Puerto Rico, or the U.S. Virgin Islands).

(iv) <u>52.222-35</u>, Equal Opportunity for Veterans (JUN 2020) (<u>38 U.S.C.</u> <u>4212</u>) (Applies to contracts valued at or above the threshold specified in FAR <u>22.1303</u>(a) on the date of award of this contract).

(v) <u>52.222-36</u>, Equal Employment for Workers with Disabilities (JUN 2020) (<u>29 U.S.C. 793</u>) (Applies to contracts over the threshold specified in FAR <u>22.1408</u>(a) on the date of award of this contract, unless the work is to be

performed outside the United States by employees recruited outside the United States). (For purposes of this clause, "United States" includes the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.)

(vi) <u>52.222-37</u>, Employment Reports on Veterans (JUN 2020) (<u>38 U.S.C. 4212</u>) (Applies to contracts valued at or above the threshold specified in FAR <u>22.1303</u>(a) on the date of award of this contract).

(vii) <u>52.222-41</u>, Service Contract Labor Standards (AUG 2018) (<u>41 U.S.C. chapter 67</u>) (Applies to service contracts over \$2,500 that are subject to the Service Contract Labor Standards statute and will be performed in the United States, District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, Johnston Island, Wake Island, or the outer Continental Shelf).

(viii) (A) <u>52.222-50</u>, Combating Trafficking in Persons (OCT 2020)(<u>22 U.S.C. chapter 78</u> and E.O. 13627) (Applies to all solicitations and contracts).

(B) Alternate I (MAR 2015) (Applies if the Contracting Officer has filled in the following information with regard to applicable directives or notices: Document title(s), source for obtaining document(s), and contract performance location outside the United States to which the document applies).

(ix) 52.222-55, Minimum Wages Under Executive Order 13658 (Nov 2020) (Applies when 52.222-6 or 52.222-41 are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia)).

(x) <u>52.222-62</u>, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706) (Applies when <u>52.222-6</u> or <u>52.222-41</u> are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia.))

(xi) <u>52.223-5</u>, Pollution Prevention and Right-to-Know Information (MAY 2011) (E.O. 13423) (Applies to services performed on Federal facilities).

(xii) <u>52.223-11</u>, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693)(applies to contracts for products as prescribed at FAR <u>23.804(a)(1)</u>). (xiii) <u>52.223-12</u>, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693) (Applies to maintenance, service, repair, or disposal of refrigeration equipment and air conditioners).

(xiv) <u>52.223-15</u>, Energy Efficiency in Energy-Consuming Products (MAY 2020) (<u>42 U.S.C. 8259b</u>) (Unless exempt pursuant to <u>23.204</u>, applies to contracts when energy-consuming products listed in the ENERGY STAR® Program or Federal Energy Management Program (FEMP)) will be-

(A) Delivered;

(B) Acquired by the Contractor for use in performing services at a Federally-controlled facility;

(C) Furnished by the Contractor for use by the Government; or

(D) Specified in the design of a building or work, or incorporated during its construction, renovation, or maintenance).

(xv) <u>52.223-20</u>, Aerosols (JUN 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons as a propellant or as a solvent; or contracts for maintenance or repair of electronic or mechanical devices).

(xvi) <u>52.223-21</u>, Foams (JUN 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons as a foam blowing agent; or contracts for construction of buildings or facilities.

(xvii) <u>52.225-1</u>, Buy American-Supplies (JAN 2021) (<u>41</u> <u>U.S.C. chapter 67</u>) (Applies to contracts for supplies, and to contracts for services involving the furnishing of supplies, for use in the United States or its outlying areas, if the value of the supply contract or supply portion of a service contract exceeds the micro-purchase threshold, as defined in FAR <u>2.101</u> on the date of award of this contract, and the acquisition-

(A) Is set aside for small business concerns; or

(B) Cannot be set aside for small business concerns (see $\underline{19.502-2}$), and does not exceed \$25,000).

(xviii) <u>52.226-6</u>, Promoting Excess Food Donation to Nonprofit Organizations., Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) (<u>42 U.S.C. 1792</u>) (Applies to contracts greater than the threshold specified in FAR <u>26.404</u> on the date of award of this contract, that provide for the provision, the service, or the sale of food in the United States).

(xix) <u>52.232-33</u>, Payment by Electronic Funds Transfer-System for Award Management (OCT 2013)(Applies when the payment will be made by electronic funds transfer (EFT) and the payment office uses the System for Award Management (SAM) as its source of EFT information).

(xx) <u>52.232-34</u>, Payment by Electronic Funds Transfer-Other than System for Award Management (JUL 2013) (Applies when the payment will be made by EFT and the payment office does not use the SAM database as its source of EFT information).

(xxi) <u>52.247-64</u>, Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) (<u>46 U.S.C. App. 1241</u>) (Applies to supplies transported by ocean vessels (except for the types of subcontracts listed at <u>47.504(d)</u>).

(2) Listed below are additional clauses that may apply:

(i) <u>52.204-21</u>, Basic Safeguarding of Covered Contractor Information Systems (JUN 2016) (Applies to contracts when the contractor or a subcontractor at any tier may have Federal contract information residing in or transiting through its information system.

(ii) <u>52.209-6</u>, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (JUN 2020) (Applies to contracts over the threshold specified in FAR <u>9.405-2</u>(b) on the date of award of this contract).

(iii) <u>52.211-17</u>, Delivery of Excess Quantities (*Sept* 1989) (Applies to fixed-price supplies).

(iv) <u>52.247-29</u>, F.o.b. Origin (FEB 2006) (Applies to supplies if delivery is f.o.b. origin).

(v) 52.247-34, F.o.b. Destination (Nov 1991) (Applies to supplies if delivery is f.o.b. destination).

(c) *FAR 52.252-2, Clauses Incorporated by Reference (Feb 1998)*. This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

[Insert one or more Internet addresses]

(d) *Inspection/Acceptance*. The Contractor shall tender for acceptance only those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. The Government must exercise its post acceptance rights-

(1) Within a reasonable period of time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(e) *Excusable delays*. The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence, such as acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(f) *Termination for the Government's convenience*. The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the

notice of termination, plus reasonable charges that the Contractor can demonstrate to the satisfaction of the Government, using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred that reasonably could have been avoided.

(g) *Termination for cause*. The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(h) *Warranty*. The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(End of clause)