STATEMENT OF NEED (SON)

<u>Instructions:</u> This document should be used for the acquisition of PRODUCTS. Instructions for completion are in red, and should be excluded in the completed document.

1.0 TITLE

Gas Permeable Flask for Surgery Branch clinical protocols.

2.0 BACKGROUND

Wilson Wolf Manufacturing produces a series of gas permeable flasks which have been used successfully to expand patient cells for adoptive cell therapy. These flasks are critical for the successful expansion of patient cells, to high densities, under static conditions, while providing enhanced aeration. Static culture conditions are essential for the early stages of lymphocyte expansions, where uninterrupted contact with feeder cells is necessary to provide the essential costimulatory signals to initiate a successful patient treatment. We will use these gas permeable flasks to expand patient cells and These flasks allow the high-density growth needed to achieve the clinically relevant cell numbers required to treat patients on NIH/NCI/Surgery branch protocols.
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3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

While other bioreactors do exist, none are in this format. Wilson Wolf bioreactors have been validated and approved by the FDA in our protocols. Switching to a different bioreactor would require validating new bioreactors clinically, rewriting all protocols, and resubmitting them to the FDA for approval.

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

- **High cellular concentration**
- **Easy of feeding**
- **Established growth curves**

4.2 DELIVERY / INSTALLATION

Thomas Shelton
Building10, CRC Rm 3W-3808,
10 Center Dr
Bethesda, MD 20892
240-858-3070
Thomas_Shelton@NIH.gov

Delivery within 2 weeks of order.

4.3 TRAINING

No training needed

5.0 PAYMENT

Please provide the payment frequency if known (monthly, monthly in arrears, quarterly, etc.).

Payment shall be made once. Payment authorization requires submission and approval of invoices to the 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 <u>INVOICE REQUIREMENTS</u>

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.