STATEMENT OF WORK (SOW)

1.0 TITLE

InterpFlow Flow Cytometry Data Analysis

2.0 BACKGROUND

Flow Cytometric immunophenotyping is standard medical care for patients with hematolymphoid malignancies and therefore is a necessary clinical service for NCI patients enrolled in clinical trial studies. The Flow Cytometry Unit in the Laboratory of Pathology is the only NIH laboratory providing standard diagnostic flow cytometric evaluation of neoplastic specimens using unique and highly complex flow cytometric testing mandated by numerous NCI protocols and unavailable at any commercial laboratory or any single academic pathology laboratory.

2.1 OBJECTIVE

The Work to be performed is analysis of unique and complex specimens and is essential to ensure patient results are reported timely as the patient workload has increased beyond the capacity of the department pathology staff. The source can provide the necessary expertise to ensure data analysis fulfills patient care responsibilities with a significant savings to the government by accommodating the workload without an additional FTE pathologist salary. Salary and benefits would easily exceed $250,000 per year for a board-certified pathologist.

3.0 SCOPE

Contractor to provide remote flow cytometry analysis of 650 flow cases (FCS files) generated by the NCI flow cytometry clinical laboratory. The NCI shall begin transfer of cases to the Contractor immediately upon award of the contract. Contractor shall receive data and perform analysis daily. Service shall be performed by technically qualified flow cytometry analysts. Service shall consist of 1) receipt of flow cytometry listmode data (raw data directly generated from the flow cytometry) through a secure data transfer mechanism such as Box.com (already in place) or other means according to NIH IT security requirements; 2) analysis of patient flow cytometry data; 3) reporting of interpreted data in the form of flow cytometry analysis documents to be retrieved by the NCI flow cytometry lab through the secure data transfer mechanism such as Box.com or other means according to NIH IT security requirements. Analysis of cases shall be completed in 1 business day for routine cases and no longer than 12 hours for rush cases.

STATEMENT OF WORK (SOW)

4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS

Contractor shall perform the following tasks and provide documentation on demand for all of the following personnel qualifications:

4.1 Contractor to provide service by case as remote flow cytometry analysis of FCS files generated by the NCI flow cytometry clinical laboratory. The NCI shall begin transfer of cases to the Contractor immediately upon award of the contract. Service shall be performed by technically qualified flow cytometry analysts.

4.1.1 Contractor shall receive flow cytometry cases daily as flow cytometry listmode data (raw data directly generated from the flow cytometer) through a secure data transfer mechanism such as Box.com (already in place) or other means according to NIH IT security requirements.

4.1.2 Contractor shall analyze each case using one or more FCSExpress templates or create analysis as appropriate for the diagnosis.

4.1.2.1 Contractor will contact NCI flow cytometry lab via email to resolve unexpected findings or incongruous results as appropriate.

4.1.2.2 NCI flow cytometry pathologists will contact Contractor via email to expedite urgent need for rapid case analysis performance by Contractor

4.1.3 Contractor shall return the completed case as FCSExpress analysis documents for retrieval by the NCI flow cytometry lab through the secure data transfer mechanism such as Box.com or other means according to NIH IT security requirements.

4.1.4 Contractor due date for case return will vary according to NCI flow cytometry case urgency (see 4.1.2.2) and # of cases per day as follows:

4.1.4.1 Urgent need cases returned no longer than 12 hours

4.1.4.2 Normal workload (0 – 10 cases) returned within 1 day

4.1.4.3 Heavy workload (10 – 20 cases) returned within 2 days

4.1.4.4 Bolus workload (>20 cases) decided by NCI pathologists

4.2 The Contractor will have the following software and case experience qualifications.

4.2.1 Contractor will have minimum 10 years' experience with DeNovo analysis software FCSExpress (RUO) and current working knowledge and experience with FCSExpress version 7.

4.2.2 Contractor will have minimum 10 years' experience with majority experience performing analysis of minimal residual disease (MRD) in a wide variety of human cancers inclusive of, but not limited to, hairy cell leukemia; pediatric non-responsive ALL; AML; MGUS; T cell leukemia/lymphoma, Follicular Cell Lymphoma (FCL), Mantle Cell Lymphoma (MCL) and Plasma Cell leukemia.

4.2.3 Personnel qualifications must be provided for each employee showing evidence of primary, independent, minimum number of case analyses for each of the following conditions:
4.2.3.1 Hairy cell leukemia cases: minimum 500 MRD cases
4.2.3.2 Pediatric non-responsive ALL: minimum 500 MRD cases
4.2.3.3 AML: minimum 100 cases
4.2.3.4 MGUS/Plasma cell leukemia: minimum 500 MRD cases
4.2.3.5 FCL/MCL: minimum 500 MRD cases
4.2.3.6 CAR-T cell therapy (ALL): 500 cases
4.2.3.7 CAR-T cell therapy (AML): 100 cases

5.0 TYPE OF ORDER

This is a firm fixed price purchase order.

6.0 PERIOD OF PERFORMANCE

From June 24, 2021 to June 1, 2022 *(or to the date that the P.O. is received in full, whichever comes first).*

7.0 PLACE OF PERFORMANCE

Contractor to provide remote flow cytometry analysis through a secure data transfer mechanism such as Box.com (already in place) or other electronic means according to NIH IT security requirements.

8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

Contractor to return each analyzed case with completed analysis using FCSExpress analysis templates and software to the NCI flow cytometry clinical laboratory via transfer by Box.com or other means according to NIH IT security requirements. Contractor daily case volume is variable without warning, therefore the due date for analysis return is dependent on individual case urgency and on case volume which may bolus (> 20 cases) or lapse (0).

All deliverables shall be sent electronically per the following deliverable schedule after file transfer:

DELIVERABLE	DELIVERABLE DESCRIPTION / FORMAT REQUIREMENTS	DUE DATE
4.1.4.1	Case: Urgent analysis / FCSExpress analysis files	12 hours
4.1.4.2	Case: received as 1 – 10 cases / FCSExpress analysis files	1 day
4.1.4.3	Case: received as 11 – 20 cases / FCSExpress analysis files	2 days
4.1.4.4	Case: received as > 20 cases / FCSExpress analysis files	Individual decision by NCI flow cytometry pathologist

STATEMENT OF WORK (SOW)

9.0 PAYMENT

Payment shall be made monthly. 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 <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.*

STATEMENT OF WORK (SOW)

* 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.