STATEMENT OF WORK (SOW)

<u>Instructions:</u> 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

Guardant360 testing in cancer patients treated with immunotherapy

2.0 BACKGROUND

The FDA recently approved immunotherapy for patients with microsatellite instability (MSI hi) and later high tumor mutation burden (TMB hi) tumors. Many cancers, such as prostate cancer, have disease that is not amenable to biopsy to obtain MSI or TMB status. Guardant360 CDx is the first FDA-approved comprehensive liquid biopsy for all advanced solid tumors. By simply taking a blood sample, this company can provide information on MSI and TMB status. The MSI hi status in prostate cancer is about 5% in the advanced disease setting.

2.1 OBJECTIVE

The primary objective is to find out the MSI and TMB status on men enrolled in the clinical trial NCT03493945 also known as QuEST.[i] This is an ongoing immunotherapy study in men with metastatic prostate cancer whose disease has progressed despite standard hormonal therapy. A substantial proportion of men have responded to our combination immunotherapy and we want to understand the mechanism and to rule out if it is related to TMB / MSI status. The only way to do this without an invasive procedure in these men is to obtain the Gurdant360 test. This is critical for understanding the true impact of this combination immunotherapy approach on the field.

More broadly, this could also be applied to other patients who don't have readily available tumor for analysis since the FDA approvals are tissue agnositic.

3.0 SCOPE

Guardant360 sequences 83 cancer-associated genes to identify somatic alterations. Cell-free DNA (cfDNA) is extracted from plasma, enriched for targeted regions, and sequenced using the Illumina platform and hg19 as the reference genome. The types of genomic alterations detected by Guardant360 include single nucleotide variants, gene amplifications, fusions, short insertions/deletions and splice site disrupting events. Microsatellite Instability (MSI) is assessed for all cancer types by evaluating somatic changes in the length of repetitive sequences on the Guardant360 panel. Tumor mutational burden (TMB) score is calculated for all cancer types

from somatic SNVs and indels in exons of ~500 genes detected in cfDNA, followed by adjusting for tumor shedding levels and the size of the panel.

4.0 CONTRACT REQUIREMENTS/ AND PERSONNEL QUALIFICATIONS (IF APPLICABLE)

N/A

5.0 TYPE OF ORDER

Patient sample testing with a firm fixed price per patient sample. There will be four patients.

6.0 PERIOD OF PERFORMANCE

The period of performance shall be for 12 months from date of award.

7.0 PLACE OF PERFORMANCE

Guardant 360

8.0 REPORT(S)/DELIVERABLES AND DELIVERY SCHEDULE

All reports shall be sent electronically via portal or fax after the patient sample testing has been completed.

9.0 PAYMENT

Payment shall be made *after invoicing based on when samples are collected and processed*. 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) 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

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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.

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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.

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[i] Redman JM, Steinberg SM, Gulley JL. Quick efficacy seeking trial (QuEST1): a novel combination immunotherapy study designed for rapid clinical signal assessment of metastatic castration-resistant prostate cancer. *J Immunother Cancer*. 2018;6:91. PMCID: PMC6145343