

| | | | | |
|---|---------------------------------|---|--|---|
| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT | | | 1. CONTRACT ID CODE | PAGE OF PAGES 1 4 |
| 2. AMENDMENT/MODIFICATION NO. Amendment Six (6) | 3. EFFECTIVE DATE 12/11/2015 | 4. REQUISITION/PURCHASE REQ. NO. | 5. PROJECT NO. (If applicable) | |
| 6. ISSUED BY National Cancer Institute Office of Acquisitions, TSB Riverside Five, Suite 400 8490 Progress Drive, Room 4036 Frederick, MD 21701-4998 | CODE | 7. ADMINISTERED BY (If other than Item 6) | CODE | |
| 8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) All potential offerors. | | | <input checked="" type="checkbox"/> 9A. AMENDMENT OF SOLICITATION NO. RFP N02CO54417-02 | <input checked="" type="checkbox"/> 9B. DATED (SEE ITEM 11) 07/30/2015 |
| | | | <input type="checkbox"/> 10A. MODIFICATION OF CONTRACT/ORDER NO. | <input type="checkbox"/> 10B. DATED (SEE ITEM 13) |
| CODE | FACILITY CODE | | | |

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:
 (a) By completing items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

**13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.**

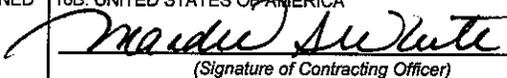
| | |
|-------------------------------------|---|
| CHECK ONE | A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. |
| <input type="checkbox"/> | |
| <input type="checkbox"/> | B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b). |
| <input type="checkbox"/> | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: |
| <input checked="" type="checkbox"/> | D. OTHER (Specify type of modification and authority) Amend applicable sections of the RFQ and provides responses to questions received. |

E. IMPORTANT: Contractor is not, is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this amendment is to amend sections of the RFQ and provide responses to questions received as described in the attached amendment document.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| | | | |
|---|------------------|---|------------------------------|
| 15A. NAME AND TITLE OF SIGNER (Type or print) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Mandie S. White, Contracting Officer, NCI | |
| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA  (Signature of Contracting Officer) | 16C. DATE SIGNED 12/11/15 |
| (Signature of person authorized to sign) | | | |

RFQ Number: N02CO54417-02, Total 100% Small Business Set-Aside

Amendment No. Six (6)

National Institutes of Health (NIH), National Cancer Institute (NCI)

Office of Acquisitions (OA), Treatment and Support Branch (TSB)

Date of Issuance: December 11, 2015

The above numbered Request for Quotation (RFQ) is amended as set forth below. Specifically, all clinical data shall be sent to the CDR versus the BCR. This Amendment also incorporates all of the changes from previous Amendments into a revised RFQ document and provides responses to questions received. The hours and dates specified for receipt of responses remains unchanged.

Therefore, this Amendment #6 revises the subject Request for Quotation (RFQ) as follows:

- 1. Section 2 Statement of Work for CPTAC Biospecimens**, paragraph 1 and bullet 1 hereby read as follows. Changes are in bold:

To meet CPTAC goals, NCI will award multiple indefinite delivery/indefinite quantity commercial item purchase order awards to organizations (Contractors) that will deliver clinically annotated biospecimens. The tissues and **non-clinical data** will be delivered to one of CPTAC's Biospecimen Core Resource(s) (BCR) for storage, quality control, processing into molecular analytes, and other research efforts. **Clinical data shall be supplied to the Comprehensive Data Resource (CDR)**. The histological specifications and annotation requirements of the cancers to be studied by CPTAC, the number of cases and biospecimens required per cancer, and preferred timing for their delivery to a BCR will be specified within each individual delivery order issued under the indefinite delivery/indefinite quantity purchase order.

In performance of this purchase order, the Contractor shall ensure that:

- All biospecimens and data (**other than Case Report Forms [CRFs]**) must be shipped directly from the contractor to a CPTAC BCR. The Government will identify the BCR responsible for receiving the biospecimens and data and will provide this information to the contractor prior to packaging and shipping of the biospecimens.

The remainder of this section remains unchanged.

- 2. Section 2.1.2 Specification of Cancers to be Collected**, states that *"This list [Appendix B] is preliminary and is subject to having cancers added or eliminated."* Therefore, Acute Myeloid Leukemia (AML) is closed and eliminated from Appendix B: List of Cancers.

The remainder of this section remains unchanged.

- 3. Section 2.1.4.1 Data requirements for CPTAC**, bullet 4 hereby reads as follows. Changes are in bold:

For each CPTAC case of biospecimens provided to CPTAC, the following data shall be provided:

- Baseline and Supplemental Case Report Forms (CRF) data, **to be submitted to the Comprehensive Data Resource (CDR)** once BCR has notified the contractor that the specimens have passed relevant Quality Control steps.
 - To receive Payment 3, 100% of data elements are required.
 - Data must be delivered within thirty (30) calendar days of BCR notification

The remainder of this section remains unchanged.

4. Section 2.2 Payment Schedule for Biospecimens and Data and Other Applicable Information, bullets 3 and 5 hereby read as follows. Changes are in bold:

1. A case is defined as all of the components identified in Payments 1 – 4. For CPTAC designated cases, NCI will make fractional payments on the total per case price according to the following milestones:
 - Payment 3 (15% of total fixed price per case): Upon delivery of Enrollment, Follow- Up (if available) and Supplemental data case report forms to the **CDR** within 30 calendar days of being notified that a case's biospecimens have passed BCR QC. Contractors will be required to provide a refund or replacement case at the discretion of the COR, at no cost to the Government if these data cannot be provided within 6 months after receipt of the request. A formalin fixed paraffin embedded (FFPE) slide or images from the FFPE diagnostic block shall be submitted at this time for all qualifying cases.
 - Payments 5 and 6: Additional completed Follow-Up data (see payment 4 for details) are requested from sites to improve the overall data on the CPTAC cohort. Additional annual follow-up forms with related treatment data can garner additional follow-up payments, deemed payments 5 and 6 (for example, depending upon the receipt of sample(s), groups could provide one in 2015 and one in 2016). Additional Payments 5 and 6 may be offered, when funding remains available, to sites for those samples that have already provided approved data equivalent to that described in payment 4. At one year intervals, sites can coordinate with the NCI COR to provide additional follow-up data on still living patients or patients that have died since the prior follow-up/treatment forms were submitted to the **CDR**. Payments 5 and 6 are hereby added in an effort to replace payments that were not previously utilized for payments 1, 2, 3 or 4 either due to no delivery or cases that did not pass QC.

The remainder of this section remains unchanged.

Inquiry 1 –

Question: We are an international company. Our clinics [and] collection sites are located in Kiev, Ukraine.

a. Are we financially responsible for NCI to visit Kiev for clinical auditing?

- b. All clinical materials are obtained following validated protocols, in conjunction with Institutional Review Board (IRB)/Ethical committee's approvals in Kiev. Can you accept Kiev IRB approval?
- c. Due to the deadline approached, can we submit our application on line?

Response:

- a. No, if an audit becomes necessary, NCI will cover the cost of travel for anyone who attends on behalf of NCI.
- b. Yes, provided that the IRB approval is consistent with NCI requirements.
- c. There is no online application process. Please follow the instructions within the RFQ and submit responses electronically to whitems@mail.nih.gov and tcirilley@mail.nih.gov on or before the final closing date of December 17, 2015 at 3pm EPT.

END OF AMENDMENT #6.