

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE	PAGE OF PAGES 1 4
2. AMENDMENT/MODIFICATION NO. Amendment Four (4)		3. EFFECTIVE DATE 10/01/2015	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.**

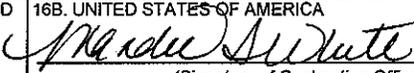
<input type="checkbox"/>	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
<input type="checkbox"/>	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in 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) Responses to questions received and amend sections of the RFQ.

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 modification is to provide responses to questions received between 9/4/15 and 9/23/15 and to amend sections of the RFQ as described in the attached amendment.

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 10/1/15
(Signature of person authorized to sign)			

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

Amendment No. Four (4)

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

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

Date of Issuance: October 1, 2015

The above numbered Request for Quotation (RFQ) is amended as set forth below. This Amendment also provides responses to questions received between 9/4/15 and 9/23/15. The hours and dates specified for receipt of responses remains unchanged.

This Amendment #4 revises the subject Request for Quotation (RFQ) as follows:

1. **Section 2.2 Payment Schedule for Biospecimens and Data and Other Applicable Information**, the below is hereby added:
 - All deliverables and correspondence must be in English.
 - NCI will contact the contractor with regards to the Material Transfer Agreement(s) between the contractor and the BCR.
2. **Section 7. To be Submitted with Offeror's Proposal**, the below is hereby added:
 - A list of proposed tumor types and for each:
 - The number expected to ship to the BCR;
 - The number expected to qualify at the BCR and;
 - The number expected to receive enrollment and 1 year follow-up CRFs.
3. **Section 8. Purchase Order Clauses and Terms, Deliveries and Acceptance**, hereby adds the following reporting requirements:

Monthly Status Reports

Acceptance of a Monthly Status Report shall initiate payment of a given case. Monthly Reports shall contain a list of all contracted tumor types and the number of cases in each of the stages listed below:

- Shipped to the BCR;
- Qualified at the BCR;
- Baseline CRFs submitted to the BCR;
- 12 month annual follow-up CRFs submitted to the BCR

Monthly Status Reports shall include a description of the activities completed during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

Monthly Status Report shall be due on or before the 30th calendar day following each reporting period and shall be sent electronically to the Contracting Officer and Contracting Officer's Representative.

Final Report

A Final Report is to include a summation of the work performed and results obtained for the entire contract period of performance to include, but not limited to the information contained in the monthly status reports. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be due on or before the expiration date of the IDIQ contract and shall be sent electronically to the Contracting Officer and Contracting Officer's Representative.

Inquiry One

Question 1: May we have an example of the [below] forms that are requirements of the RFQ?

- Biospecimen Case Control Form
- Submission Case Report
- Baseline and Supplemental Case Report Forms

Response 1: These forms are currently being drafted and will be provided upon completion.

Inquiry Two

Question 1: We have lung cancer biospecimens that we would be able to supply, however before assembling and submitting a proposal we would like to confirm that the CPTAC is still in need of lung cancer biospecimens. Is this cancer type still needed?

Response 1: Yes.

Question 2: Are there any cancer types that were on original list that are no longer needed?

Response 2: No.

Question 3: Have additional cancer types been added?

Response 3: No.

Inquiry Three

Question 1: Can you please comment if the submitted cases need to be collected in a prospective manner? [Our organization] does have an extensive retrospective collection and likely have some cases that meet the criteria. We plan to make mention of the potential retrospective cases in the application, if applicable.

Response 1: NCI would like to know how many retrospective cases meet the CPTAC criteria. However, at present, only prospective cases will be considered.

Question 2: Our understanding is that we can use our internal consent that covers remnant tissue and blood consent, just as we did for TCGA. Please confirm that this is correct and that a new consent, unique for this study will not need be required.

Response 2: Yes, an existing internal consent that allows for general research use is acceptable for this collection.

Question 3: Is it a requirement if the frozen tissue and blood need to be submitted at the same time? When sample submission was underway for TCGA, we were allowed to submit the tumor tissue to the BCR, wait to learn which tumor tissues passed QC metrics, and then send blood only for the qualified tumors.

Response 3: Yes, the tissue and blood samples shall be shipped in the same shipment. Currently, the CPTAC workflow initiates with the BCR sending a kit for tissue and blood collection. The TSS then ships all components of the kit to the BCR in one shipment.

Question 4: Can you please comment if adjacent non-tumor tissue is a requirement or a preference in addition to the blood?

Response 4: For most tumor types, adjacent non-tumor tissue is required for comparative proteomic analysis. Exceptions include GBM and AML.

Inquiry Four

Question 1: Can you clarify if whether we are able to use our own Material Transfer Agreement (MTA) or obligated to use the MTA template provided?

Response 1: Yes, you may use your own MTA.

Question 2: If yes, should our template be submitted with the response for review?

Response 2: No, you do not submit the MTA. The NCI is not a party to the MTA. The MTA is between the TSS and the BCR.

END OF AMENDMENT #4.