



Frederick

AMENDMENT OF SOLICITATION

SOLICITATION/RFP NUMBER S13-088	AMENDMENT NUMBER 03	EFFECTIVE DATE Date of SAIC-Frederick Signature	PAGE 1 of 6
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OFFEROR NAME AND ADDRESS:	ISSUED BY: SAIC-Frederick, Inc. Research Contracts P.O. Box B Frederick, MD 21702-1201
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The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of offers is extended, is not extended.

DESCRIPTION OF AMENDMENT:

The purpose of this amendment is to:

1. Incorporate the Pre-Proposal Bidder's Questions and Answers – See Attachment 1
2. Update Request for Proposal (RFP) Attachment 3 Subcontract Cost (or Price) Proposal Information – See Attachment 2
3. Provide Revised Cost Proposal Templates – **See Separate Document Titled "Revised Cost Proposal Templates"**

**** ALL OTHER TERMS & CONDITIONS REMAIN UNCHANGED AND IN FULL FORCE AND EFFECT ****

For Offeror: N/A		For SAIC-Frederick, Inc.:	
Name	Date Signed:	Name: Shaneeka Owens	Date Signed:
Title		Title: Sr. Subcontract Administrator	14 Feb 2013

Attachment 1

- **Pre-Proposal Bidder's Questions and Answers:**

Q1. Page 1 – We need some clarification on the 5 year CRF's – they do not appear to be part of the original submission but will require a lot of time and effort to complete so how do we determine costs and funding for that work?

A1. Completing the five year CRFs is not within the scope of the solicitation. Offerors need not attempt to determine costs. The information regarding a five year follow up was inserted into the RFP to fully describe overall CPTAC Program objectives.

Q2. Do all changes in key personnel need to be reported to the Contracting Office – over the life of the proposal there could be changes in lab personnel, other key personnel, as well as PIs. In addition, due to the type of personnel needed for specimens processing, will we be submitting costs based on personnel to be determined at a later time?

A2. Only one person, the PI/Project Manager is required to be designated a "Key Personnel." Given the firm-fixed pricing of the final agreement, changes in other personnel not designated as "Key" need not be reported to SAIC-Frederick. Submitting cost proposals based on prevailing labor rates for specific positions at the offerors institution although the position will be filled at a later date is acceptable. SAIC-Frederick may request that a CV for the individual ultimately filling the position be submitted to ensure the individual's background and skills are consistent with the position and costing.

Q3. We need a clarification on the # of specimens – is the 125 number the total number of specimens to be collected by all tissue collection sites or is the expectation that each site will contribute 125 specimens per tissue site considering there is a 12 month time frame listed? Do we contract for a set number?

A3. The goal of the CPTAC Program is to accumulate at least 100 qualified samples from each of the three types of cancer to be studied. SAIC-Frederick and the NCI CPTAC Program Office make the assumption that reaching that goal will require obtaining tissue from at least 125 volunteer patients suffering from each of the cancers. An additional goal of the program is for the majority of the patients to be enrolled and tissue collected during the first year of the Period of Performance with patient follow up occurring during the second year. There is no requirement that any one site submit all the qualified samples for a cancer nor is there a requirement for all samples to be obtained during the first year of the Period of Performance. Offerors are asked to estimate in their proposals how many total cases they expect to see during the Period of Performance; multiple subcontracts may be awarded based on the responses maximizing the likelihood that the CPTAC Programs goals are achieved. If needed, individual subcontracts may be modified with time extensions to reach the numeric goals of the CPTAC Program.

Q4. Does the base period of performance for 12 months refer to 12 months for submission of specimens or does it include the data submission as well? Is the additional 12 month option just for data collection or can specimens be submitted in that period of time as well. Again, still need clarification of the 5 year data collection as time and effort needs to be addressed and the protocol would have to stay open at the IRB until all data collection is completed. See also Pg 22 F.6.b

A4. Please see the response to Q3. Also, the RFP will be further amended to reflect a single, two year Period of Performance instead of a one year base period and one year option period. As noted in the response to Q1, the five year follow up is not within the scope of this solicitation.

Q5. How many unstained slides would be needed as this has to be addressed in the budget as a path cost.

A5. Ten unstained slides from FFPE sections are only required for breast cancer (Please see the Tumor Procurement Protocols in the Appendix). Representative images the H&E stained slides used to determine the histopathologic diagnosis are required for all cancer types. The number of images that provide a “representative” histopathological view of the tumor is left to the judgment of the offeror and pathologist. If images are not readily available, the site is required to provide representative stained slides to the BCR vendor for images. In that case, the physical slides will be returned to the site and all shipping costs covered by the BCR. Any pathology costs incurred should be included in the total costs proposed to SAIC-Frederick.

Q6. Please define “end of original treatment regimen”? Does this include maintenance therapy give as part of the initial treatment regimens as this could extend the completion of treatment out to 22 months form date of first treatment.

A6. The intent of the patient follow up is to provide clinical information that might be useful for proposing follow on studies testing hypotheses that may emerge from the novel, multidimensional data sets expected from the CPTAC Phase II work. With that said, the intent of “original treatment regimen” was to describe a regimen based on a defined number of cycles of therapy with each cycle lasting a few weeks (e.g., a chemotherapy regimen of three week cycles X six cycles). This is an arbitrary definition and the question indicates the definition may not be suitable in many cases to allow the one year follow up to fall within a two year Period of Performance even with modest time extensions. This question will be taken to the relevant CPTAC Working Group for consideration. Offerors should assume that a follow up of approximately one year will be required for all cases although the definition of the starting point for the follow up may be modified.

Q7. What is the time frame for storage of tissue by the biorepositories this is a question that comes up frequently in IRB submissions.

A7. The intent is to securely maintain any tissues remaining after the first round of processing for proteomic and genomic analyses as a resource for follow on studies by the CPTAC Program. It is recognized that limitations to usage will exist and additional permissions or modifications to the MTA/DUAs for any subsequent use will likely be needed.

Q8. Is the Clinical Collection Form to be submitted with the tissue to be filled out as a paper form or is there an electronic form that is printed and sent with the specimens?

A8. It is envisioned that all biospecimen and clinical data will be submitted electronically. If needed, the BCR will be able to provide paper documents and will be responsible for entering data into the electronic systems. One exception is that the site will be required to prepare a physical manifest for each shipment. The BCR will provide guidance on the form and format to be used for the manifest.

Q9. Do sites get paid for cases submitted but which do not qualify? This will be an issue for the ovaries

as only high grade, high stage serous are eligible and we would have to process each surgical case as if it were eligible, only submitting those where the final path meets histologic eligibility.

A9. The basis for estimating costs has been modified and a revised cost worksheet provided to account for this scenario.

Q10. Page 36 Inclusion criteria for ovarian specimens – are all histologic types included if they are high grade or only serous? Are cases with mixed histology eligible if one of the histologies is serous (i.e. mixed serous and clear cell)? The H&E slides needed – how many slides are required as this will also affect our pathology costs.

A10. This will be addressed on a case-by-case basis in consultation with an appropriate CPTAC Working Group.

Q11. Is the 200 mg weight the total of all specimen pieces being sent – if 2 strips are being sent must they be 100 mg each?

A11. The total weight required is 200 mg. If two strips are sent, efforts should be made so they are each approximately 100 mg.

Q12. Is there a draft consent?

A12. No. Bidders are free to use a form consistent with local practices. Note that Appendix 3 in the RFP provides information on which to develop the consent form.

Q13. Please clarify the timing of the blood draw – must it be done immediately pre-op in the pre-op area; can it be done if the patient’s pre-meds are already on board; can it be done when the patient is already under anesthesia but before the first surgical cut?

A13. The blood draw shall be performed prior to the patient’s surgical premeds.

Q14. Is a description of the facilities to be used required?

A14. A brief description is required, especially the ultra-cold storage that is available for holding the samples until shipping to the BCR.

Q15. Is the purchase of capital equipment allowed?

A15. Yes as long as it is justified.

Q16. Will tissue from a breast cancer patient undergoing neoadjuvant therapy prior to surgery be accepted?

A16. Radiation or chemotherapy for the breast cancer prior to surgery is exclusionary (CPTAC “Prospective Biospecimen Collection Protocol – Breast Cancer” v1 and v2).

Q17. Is a specific reference to the CPTAC Program required in the application for local IRB review and approval?

A17. Yes. All the procurements are prospective and with the level of sharing of tissue and data amongst the CPTAC participants and entities, the CPTAC Program and SAIC-Frederick believe this is needed as part of adequately describing the use of the tissues and data and the risks patients might be taking in participating.

Q18. In regard to storage of specimens prior to shipping, can we use liquid nitrogen tanks or must we have an ultra-cold liquid nitrogen freezer?

A18. The samples must be stored in vapor phase liquid nitrogen.

Amendment – Attachment 2

- Update Subcontract Cost (or Price) Proposal Instructions

Subcontract Cost (or Price) Proposal Information Section A is replaced in its entirety with the following:

A. Section One – Cost (or Price) Proposal

The cost (or price) proposal shall contain sufficient information to allow SAIC-F to perform an analysis of the proposed cost (or price) for the required deliverables. This information shall include the amounts of the basic elements of the proposed cost (or price) including, but not limited to, labor hour rates, travel, materials, Subcontracts.

In preparing your cost (or price) proposal, the following shall be considered:

- Offeror is to prepare their cost (or price) proposal using the Cost Proposal Worksheet provided as an attachment to this RFP and submitted with Offer in Microsoft Excel format.
- **Costs shall be broken out by deliverable and shall be based on the total number of cases expected to be needed to achieve the proposed number of fully qualified cases to be submitted to the CPTAC BCR.**
- In performance of the work, Offerors are expected to attend one CPTAC annual meeting as well as the following teleconference meetings (Travel costs shall be listed separate from deliverable costs.):
 - Kick-Off Meeting
 - Monthly Project Team Meeting
 - Monthly CPTAC TSS Program Meeting.

Offerors shall provide substantive detail regarding the cost (or price) proposed so as to enable reviewers to objectively determine the reasonableness. Failure to provide a level of detail to facilitate this determination may result in the proposal being considered nonresponsive.