



Frederick

AMENDMENT OF SOLICITATION

SOLICITATION/RFP NUMBER S14-004	AMENDMENT NUMBER 02	EFFECTIVE DATE Date Executed by SAIC-Frederick, Inc.	PAGE 1 of 7
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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 incorporate the Questions /Responses for the Specimen Retrieval System Network.

See Attachment 1 – Questions/Answers

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

For Offeror:		For SAIC-Frederick, Inc.:	
Name	Date Signed:	Name	Date Signed:
Title		Title	

Attachment 1

RFP S14-004 Specimen Retrieval System Network Questions/Answers

1. Will NCI specify further the annotation and preparation each specimen will require? That information will impact our ability to estimate availability of specimens and costs of processing.

Response: The purpose of this task order is to assess an offeror's ability to provide clinical specimens, therefore please focus your response on the types of specimens, approximate numbers and types of clinical annotation that would be available. You can estimate costs of from any type of specimen, but do include details of what the costs would cover. After sub-contracts are awarded, each new project will come in the form of specific task orders in which, specimen details such as annotation and preparation requirements will be provided and vary depending on the project. Please provide a general estimate for the specimens and an estimate range for specimens that will need additional information and/or preparation.

2. Will each task order be specific to a particular assay under development? If so, will that task order provide the specific details for specimen and data requirements?

Response: Typically each assay under development will be specified in separate task order. Specimen details and requirements will be provided with each task order and vary depending on the project.

3. Are you including both prospective and retrospective collections in the process? (We are very adept at working with prospective collections for clinical trials.)

Response: Depending on the project, there may be a need for prospective collections. To date, the majority of the specimens have come from retrospective collections. If price varies depending on collection procedures, please specify in your response.

4. Will you require a prequalification step both locally and again at the testing center (as with TCGA). Will payments be split based on success at checkpoints?

Response: All projects have a Go/No-Go phase for each milestone. Payments are subject to specimens reaching requirements specified in the task order/agreement. We do not anticipate a requiring pre-qualification procedures beyond providing specific specimen requirements outlined in each new task order.

5. It appears that all types of specimen states may be requested (fixed and embedded, snap frozen, embedded and fresh frozen, biopsies, resections, etc.). Should we list only those specimen states that we have already have in our archives or those states which we can potentially acquire when needed?

Response: Specimens and associated costs can be provided for those that are readily available and those that can be acquired; please clearly specify.

6. Will the specimen quality standards be the same as or similar to TCGA across the board or will they vary widely based on the assay? (We have a BOA and are in the final stages of completing a task order for specimens for TCGA.)

Response: Specimen requirements will be specific to the task order and will vary depending on project.

7. If the data requirements about the subjects are not established in advance, do you anticipate that at least some task orders/assays to which we provide specimens will need an additional separate IRB? Generally you must specify the data (at least broadly) to be collected at the time of application to the IRB. If you gather unspecified information at the time of specimen collection or go back to the record for different information at a later time you may need a separate IRB approval in order to meet a particular unanticipated project requirement. Getting a blanket IRB for an ill-defined data set or usage can be challenging depending on the local board. Will you require that any specific terms must be used in the consent (such as 'for use by the NCI Specimen Retrieval System' or 'for use in diagnostic assay development')?

Response: Each project will come with a detailed task order with the required attributes needed for the specimens. Specimens should be collected under an approved IRB. (The approval for delinked specimen is required to conduct medical research such as extraction of DNA/RNA, routine histological and immunohistochemical analysis). The de-identified samples will be subjected to medical research and will be subjected to DNA/RNA, histological and/or immunohistochemical analysis. This research may contain analysis to study treatment effects, demography and clinical outcome.

8. Do you have specific recommendations for bidding when the details of the specimen and data requirements are not defined? We can easily bid items that we are certain will be required (such as the QA slide review). For currently undefined items/services, like assay specific data requirements, can we submit hourly rates instead? I presume this will not be a totally fixed rate bidding process like TCGA.

Response: Rates will differ depending on specimen and data requirements. Providing the best estimate cost for specimens and data requirements along with cost ranges will be an acceptable response. In your response to this RFP, please provide an example of costs and details of what the costs will cover.

9. Do the specimens must already exist or whether the proposal allows a prospective collection of specimens. We are able to prospectively collect around 8 specimens per month of squamous

cell carcinoma of the head and neck, but may not be able to provide retrospective specimens. Any information you could provide would be very helpful.

Response: To date, the majority of the specimens have come from retrospective collections. However, prospective collection may be needed. Providing prices for both collection procedures will be considered an acceptable response.

10. Do you have any idea of the total # of cases likely needed by tumor type (hundreds, thousands, tens of thousands, etc.)?

Response: The range of 100-1,000 samples may be needed for any given tumor type.

11. Our retrospective sample collection is comprised of samples from both U.S. and foreign collaborators. Quality analysis of all samples including board certified Pathology review is done in the U.S. and all samples are banked in the U.S. Are all of these samples eligible for this RFP?

Response: We are unable to use samples collected from foreign collaborators at this time.

12. I believe the National Institute of Health accepts samples into The Cancer Genome Atlas Program (TCGA) under three different IRB approved “consent” scenarios: (1) full consent; (2) waiver of consent; and (3) CFR 46.101(b)(4) consent exemption. Will all three IRB approval scenarios be acceptable under this RFP?

Response: IRB approval for samples collected using (1) full consent; (2) waiver of consent; and (3) CFR 46.101(b)(4) consent exemption are acceptable under this RFP.

13. We were included in the first emails but didn't reply at all because we are not in the US and don't actually store any specimens. However, we have ethics approval to collect specimens ourselves on a prospective basis only for certain types of samples. These are mainly biopsies for diseases you normally do not take surgical samples from, e.g. dermatological diseases. We also collect blood samples from any autoimmune or inflammatory disease or cancer and also have ethical permission to collect bloods from various other blood diseases such as Polycythemia Vera etc. Are we, as a non-US company, allowed to bid for service to NIH in this programme?

Response: We are not accepting samples/companies outside the US at this time.

14. Would the awarded labs have the ability to retain and utilize the customized panel that will be validated and utilized for this project and trial?

Response: No. Intellectual property rights remain with the program and not the contracted/awarded labs.

15. Will most of the tissues of interest be paraffin embedded and not fresh frozen ?

Response: Each project will have unique needs, therefore both paraffin embedded and fresh frozen are of interest to the program.

16. Will it be possible to collect tissues prospectively if enough of the retrospective tissues are not available?

Response: Yes, but time for collection could be problematic if too long of a time is required based on specimen accrual rates. Again, each project will likely have unique attributes and challenges and prospective collection may be required.

17. According to our sample release SOP, the scientific review committee should review and vote before any release. How much information we will receive related to the project and users with sample requests?

Response: You will receive detailed Statements of Work (SOWs) for each project that will list specimen requirements and intended use of the specimens. This should be adequate for internal review.

18. We developed a banking SOP for sample collection, processing, tracking and releasing, will we be asked to change our SOP to accommodate any request?

Response: No

19. Is there an age limit to the samples required? May they be 15 years old or 30 days old? Or does it even matter?

Response: There is no age limit.

20. Would any “checks and balances” considerations restrict your 8 CLIA-grade laboratory contractors from competing for both clinical grade assay development and specimen retrieval for a given research grade assay?

Response: No

21. We understood ARRA funding to no longer be available after September 2013.

Is it possible to confirm that funds for associated task orders under this BOA will be available beyond September 2013 and the time frame for submitting and recovering funds for related task orders?

Amendment – Attachment 1

Response: ARRA funding at this facility run through September 2015 and SAIC-F can choose to use ARRA or appropriated funds for the task orders. Funding will be available.