OFFICE OF ACQUISITIONS
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N02CO07009-65

Amendment No.: 1

Date of Issuance: April 6, 2010

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offers is changed to **2:00 PM Eastern Prevailing Time on April 26, 2010**.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

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.

This Amendment revises the RFP as stated below:

A. Section M.4.1.a. is hereby revised and shall read as follows:

a. Name and number of already established and operating TSS members including detailed availability of pre-screened, retrospective samples.

THE REMAINING ARTICLE REMAINS UNCHANGED.

B. The following are the Government's respond to questions received with regards to this Request for Proposal.

1. Location page 1 of 28 in the SOW dated 3-15 10: It is stated that the TCGA needs an excess of 40,000 biospecimens over the course of the project. For clarification do you mean 40,000 individually biospecimens not 40,000 cases (as a case is defined on page 12)?

ANSWER: 40,000 cases

2. Location page 7 of 28 in the SOW dated 3-15-10: NCI clearly defines their requirement for whole blood as they specify the tube types for collection, however, what is the shipping format required (fresh or frozen) for blood?

ANSWER: Samples are generally shipped in cryoports (i.e. frozen).

3. Location page 8 of 28 in SOW dated 3-15-10: For the proposal, does Contractor need to disclose the exact names of its established and potential future clinical tissue source sites in its network or would code names suffice?

ANSWER: Established is preferred as it is deemed pertinent for the review panel to know exactly who the offerors are and their qualifications so we can be sure these potential sites are indeed valid and to understand whether sites have a clear understanding of TCGA protocols.

4. Location page 20 of 28 in the SOW dated 3-15-10: The Top slide procedure described in the RFP describes a procedure for obtaining a section of unfixed frozen tissue. Our pathologists prefer fixing a mirrored face of the frozen tissue to confirm diagnosis, determine percent necrosis, and percent tumor nuclei. For this TCGA project will fixing a mirrored face of the frozen tissue be comparable to the Top slide procedure as described?

ANSWER: Offerors must propose on the SOW as currently written. RFP, Page 51, Item 5, Alternate Proposals, permit the submission of alternate proposals which deviate from the requirements; provided that the offeror also submits a proposal for performance of the work specified in the statement of work.

5. Location page 75 of the RFP "4. Small Business Subcontracting Plan". For clarification if the prime on the contract is the small business, a Small Business Subcontracting plan is not required in the business proposal. Is this correct?

ANSWER: If your organization is considered a small business as defined by the Small Business Administration under the NAICS code identified for this RFP, you will not need to submit a small business subcontracting plan.

6. The RFP states that a cost-reimbursable contract will be awarded and the instructions for the business proposal pertain to drafting a cost reimbursable budget. However, the Business Proposal instructions also state that we should propose a fixed price per case per cancer and that NCI will make four payments of 25% of the total fixed price per case. Please confirm that we need to provide both types of budget information.

ANSWER: Yes. We need to clearly understand the components of your budget. Essentially, the price per case should reflect the actual costs of obtaining your specimens that are specifically delivered to a TCGA BCR. Whenever possible, an organization/institution can also provide evidence of commitment to the project through cost-sharing or other approaches to achieve the target cost estimate of ~$2,000/case. We envisioned the price of $2,000/case would cover (acquiring informed consent, sample accrual and pathology review, providing clinical data at time of sample submission and follow up data at 6 month intervals for the period of the contract). Any costs outside the price per case for network development, for example, should be proposed separately. Any cost sharing or other arrangements must be clearly identified in the technical and business proposal so that a thorough evaluation can be performed. The cost reimbursement side of the equation is for the offeror to provide a detailed accounting of their projected costs for collecting samples, based on estimated accrual rates for specific cancer types, and provide a fixed price based on those numbers. The Government must be able to verify the calculations/costs used to arrive at the fixed price per case proposed as well as the costs proposed for the entire project.

7. Attachment 1 states: It is the responsibility of the offeror to ensure that sufficient time is allotted to enter Fort Detrick, locate and deliver your proposal prior to the date and time specified for receipt of proposals." Is it sufficient to send a FedEx for morning delivery on April 15 or should we call in advance?

ANSWER: It is the offeror's responsibility to ensure that your proposal is submitted on time, including delivery by Federal Express. If you are submitting your proposal via FedEx, you will not need to call in advance. Calling in advance will not ensure that a Federal Express package will be delivered on time. We recommend calling in advance if you are having the proposal delivered by courier. Your proposal will be accepted as long as it is received prior to the proposal due date and time specified in the RFP.

8. The RFP asks for us to detail personnel costs, indirect costs and other expenses in the Business Proposal. Is this used solely to determine the reasonableness of the budget because the Statement of Work requires a fixed priced per set of tumor and blood samples that is paid in four installments?

ANSWER: Yes. These costs are requested for provision to ensure reasonableness of the budget. The payment of the fixed price per case of tissue is one component of the overall cost of the project.

9. The Statement of Work requires the collection of samples under very well defined conditions. Our current sample collections will not exactly meet these criteria. Therefore, we will be collecting new samples and can only estimate collection rates based upon previous rates. It appears that Article B.2. is requesting total costs for various contract time period. Should we estimate this based upon previous collection rates or should we just present the unit cost per sample set? Related to this, since we can only estimate the total number samples that will be collected and pass QC, but salary amount and other costs will be fixed; how should this be addressed?

ANSWER: It is your business decision as to how to propose costs. You could provide the numbers / estimates using historical data from your institution(s). The proposal should clearly identify the components of your budget. Essentially the price per case should reflect the actual costs of obtaining your specimens. Whenever possible, an institution can also provide evidence of commitment to the project through cost-sharing or other approaches to achieve the target cost estimate of ~$2,000/case. We envisioned the price of $2,000/case would cover (acquiring informed consent, sample accrual and pathology review, providing clinical data at the time of sample submission and follow up data at 6 month intervals for the period of the contract). Any costs outside the price per case for network development, for example, should be proposed separately. Any cost sharing or other arrangements must be clearly identified in the technical and business proposal so that a thorough evaluation can be performed. The cost reimbursement side of the equation is for the offeror to provide a detailed accounting

of their projected costs for collecting samples, based on estimated accrual rates for specific cancer types, and provide a fixed price based on those numbers. The Government must be able to verify the calculations/costs used to arrive at the fixed price per case proposed as well as the costs proposed for the entire project.

10. Should the Table in Article B.2. be filled out and included in the Business Proposal Section or where should this information be presented?

ANSWER: The table in ARTICLE B.2., was presented as an example as to what would appear in the resulting contract. Pricing would need to be presented in your cost proposal as specified in the RFP on page 42, Attachment 8, Excel Spreadsheet.

11. Collection rates at many of our collection sites would likely improve if we add more personnel. For example, additional personnel to explain this project and consent patients would be helpful. Likewise, more staff to expedite the pathology/collection process would also like increase collection of high quality samples. There will be a lag before this impacts sample collection rates. Can we budge for this to improve collection rates and add it into the price per sample set or should be based solely on current capabilities?

ANSWER: All costs proposed will need to be justified and supported. It is your business decision as to whether this cost is necessary for the project.

12. The Statement of Work describes a "Payment (25% of the total fixed price per case): Upon delivery of every 6 month follow-up case report form data to BCR until either the patience is deceased or the end of the contract" There could be multiple 6 months periods. How is 25% divided up or are these multiple "25%" payments for each additional follow up report for the duration of the contract? The number of follow up reports will depend upon whether or not the donor is alive and the length of the contract.

ANSWER: The last quarter, or 25%, would be paid at the conclusion of the contract. If the follow up data was provided on a specific patient for the length of the contract at each milestone/time point then a TSS would receive all 25%. If a patient passes away during follow up, as long as this is documented in data collection forms, this ceases the collection of follow-up data on that patient and would be considered completely fulfilled. If patients are lost to follow-up and no follow-up reports are provided the site would receive no fourth payment.

13. In Section K.1., Annual Representations and Certifications (a)(2) it asks for the Small Business Size Standard. What is the appropriate way to fill this out for a business of less than 20 employees? The RFP states that the size standard is 500 employees. Is this the proper answer or the actual number of employees?

ANSWER: The NAICS code is 325413 with a small business size standard of 500 employees.

14. In Section K are we required to submit a Certificate of concurrent Submission of Disclosure Statement and Form No. CASB DS-1 or CASB DS-2 with the proposal? If so, who is the official who receives these? Is there anywhere that we can obtain assistance with this part of the process?

ANSWER: If required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If a Disclosure Statement has already been submitted, you will need to complete the information requested under paragraph (c) of PART I of the CAS provision under Section K.

15. On page 75 of the RFP, it refers to a "Commercial Item Exemption". We regularly offer items that are nearly identical to what is requested in this RFP to our clients and have price lists available to verify this. Are we eligible for this exemption, and does this mean that we do not have to provide cost pricing data? Similarly, would it still be preferable to submit such data?

ANSWER: An offeror may submit a written request for a commercial item exception by providing the information identified on page 75. Please note that if an exception is not granted, the offeror will be required to prepare and submit cost or pricing data.

16. The RFP asks that we itemize all costs associated with all TSSs operating within our network. However, many of the agreements we have with the various procurement sites do not permit that level of analysis. We have typically agreed to a standard fixed price for materials obtained from our sites and itemization of all costs would jeopardize many of these relationships and reduce the number of site willing to participate. We wonder whether each TSS price analysis could be submitted as a single line item in the business proposal?

ANSWER: All costs proposed will need to be justified and documented as stated in the RFP in order that a thorough evaluation can be performed. If there are any restrictions or difficulties in providing this information, then those restrictions/difficulties should be clearly identified in the proposal.

17. The data collection forms mentioned in appendix A of the SOW as being attached as a PDF file are nowhere to be found. Can you clarify what forms you want used?

ANSWER: The generic forms are attached to these answers. That said, note that each cancer type has specific forms that are actively being developed.

18. Are there standard pathology report forms for use by the TSSs? If none exist, what clinically relevant information do you wish to have supplied?

ANSWER: The generic forms are attached to these answers. That said, note that each cancer type has specific forms that are actively being developed.

19. Currently we have MTAs in force with many of our TSSs. As we are the network hub for these sites, it serves as a useful practice to ensure that all material transfers are tightly controlled and prevents unnecessary conflicts. Instead of having each TSS develop a MTA with its BCR, can we continue in our current practice, and instead provide all accumulated TSS MTAs currently in-force to the TCGA's BCR?

ANSWER: The BCR legal teams would likely have to review the TSS MTAs to ensure that those MTAs would not be violated by a third party being introduced. If this is deemed acceptable then the situation you describe would be acceptable. In some cases the MTAs between a TSS and Tissue provider do not clearly allow for third party usage, etc.

20. Concerning data transfer and maintenance, we have maintained monitoring responsibility over the various members of our network. This enables us to ensure that what should be done, is in fact, being done. It also permits us to centralize all data feeds to our clients and precludes any confusion that might arise from using multiple feeds. It also makes life in the TSS accommodating, since all forms are prepared and all transfers accomplished in corporate facilities. Can we be permitted to continue in this manner?

ANSWER: We are unclear what you are asking. As noted in the response to Question 4, you must propose on the statement of work as currently written. Any deviations must be specified in an Alternate Proposal.

21. On page 69, the Solicitation under Information Security, NIST SP 800 53 Self Assessment, the statement is made that the offeror must include a completed Self-Assessment. Further, on page 70 under Draft Information System Security Plan, the statement is made that the offeror must include a draft Information System Security Plan. In addition to the links provided in the Solicitation, are there examples/templates of the Self Assessment and ISSP that we can reference?

ANSWER: Other than the websites provided, we are unable to give you any additional examples/templates of the Self Assessment and ISSP.

22. On page 11 of Attachment 7 (Small Business Subcontracting Plan), signature are required from the Contracting Officer, HHS Small Business Specialist and Small Business Administration Procurement Center Representative. Are we required to obtain these signatures prior to submitting our proposal?

ANSWER: No, once a sub-contracting plan is negotiated, NCI will obtain the remaining signatures.

23. On page 50 of the solicitation under Contract Type and General Clauses, the statement is made that "it is contemplated that a cost-reimbursement completion type contract will be awarded." On page 82 under Additional Cost Proposal Instructions, it states the "Offeror must proposal a total fixed price per can per cancer for this RFP . . ." Please
help us to understand how to reconcile these two statements.

ANSWER: Refer to response to question number 9.

24. Is the deadline still set at April 15th?

ANSWER: The proposal due date is being extend to April 26, 2010.

25. Is there a defined total number of specimens that are requested from a network? This wasn't clear in the proposal.

ANSWER: TCGA is looking for at least 500 qualified cases for each tumor being sought. This has historically meant the accrual of at least twice the number of specimens in order to account for tissue processing failures at the level of histology/pathology and molecular analytes. Each network should propose their accrual rates for different tumor types and TCGA will work with offerors to align the specific offers with the needs of the project. For example, for some common tumor types, TCGA might request collection for a smaller number of samples but for rarer tumors we are likely to have a greater need. The RFP is going to be used to augment our current collections so our needs will ultimately reflect how many samples have been previously accrued at the time of award.

26. Should all specimens be from one category? Eg, we might focus on bladder cancer, but may have a mixture of papillary and invasive, rather than purely one or the other.

ANSWER: We are accepting networks that can provide any mixture of the tumor types required by TCGA. Any tissues that are on the list are acceptable. Therefore, a network that could provide multiple tissues types as you describe would be preferred.

27. Are all the costs/specimen related only to reagents/manpower or is a flat fee/specimen that encompasses this without breakdown acceptable?

ANSWER: Flat fee/specimen is acceptable as longs as the proposed fee is documented and can be justified.

28. It appears that some parts of the contract should be copied and pasted into the proposal - for example, the "solicitation" component, which includes Section B.2. (page 4) that needs to be completed?

ANSWER: Section B.2. (page 2) is an example of what may appear on a resulting contract, it will depend on the type of organization that will be receiving awards. Instructions for preparing your proposal and applicable forms are under Parts III and IV of the solicitation.