



Leidos Biomedical Research, Inc.

**AMENDMENT OF SOLICITATION**

SOLICITATION/RFP NUMBER S16-001	AMENDMENT NUMBER 03	EFFECTIVE DATE October 21 2015	PAGE 1 of 11
------------------------------------	------------------------	-----------------------------------	-----------------

OFFEROR NAME AND ADDRESS:  OPEN COMPETITION	ISSUED BY:  Leidos Biomedical Research, Inc. Subcontracts Department P.O. Box B Frederick, MD 21702-1201
---	---

THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS

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 questions received with associated answers from the second Bidders Teleconference:

1. Attach questions received with associated answers from the second Bidders Teleconference of October 15, 2015. See Attachment 1;
2. No further questions will be addressed; and
3. All proposals must be received as follows:
  - Volume 1: Technical and Cost Proposal Requirements (including Offeror Signature page and completed Questionnaires from references) must be submitted by 5:00 PM ET on Thursday, November 5, 2015 to [cbcproposals@mail.nih.gov](mailto:cbcproposals@mail.nih.gov).
  - Volume 2: Compliance Document Requirements must be submitted by 5:00 PM ET on Thursday, January 14, 2016 to [cbcproposals@mail.nih.gov](mailto:cbcproposals@mail.nih.gov).

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

For Offeror: <b>NO SIGNATURE REQUIRED</b>		For Leidos Biomedical Research, Inc.:	
Name	Date Signed:	Alexander Konev	Date Signed:
Title		Contracting Officer	10/21/2015

## Attachment 1 - Questions and Answers

---

1. Will the offeror be able to include a supplemental appendix in the technical proposal?

**Answer:**

No. The technical proposal must be self-contained within the 20-page limit. Reprints of key publications are not necessary, because past performance and capabilities are integral to the technical proposal.

2. Regarding the Team and Key Personnel section, can you clarify the request to include “two or three specific examples of significant contribution which members of your team made to the performance of that team”? For large organizations, two or three examples for every team member will make it difficult to remain within the page limit.

**Answer:**

Provide a total of two or three specific examples that you consider to represent the key contributions of your staff to project teams, selected from any of your projects. The purpose of this request is for you to provide evidence of the desirable skills, abilities, or insights that your personnel can provide to NExT CBC Discovery projects, through the use of examples from past projects. The response is not expected to be a comprehensive list of accomplishments made by your scientific staff on different projects. For example, if your proposal describes capabilities in assay development, there might have been situations in which significant insight, awareness, and implementation of novel technology or rigorous evaluation of results enabled a breakthrough in efficiency or sensitivity such that a previously unmeasurable readout could now be implemented in HTS.

3. In our affiliation with an NCI designated comprehensive cancer center, certain expert services are available that have a specific cost structure. Would it be useful to provide the cost structure in the cost estimates?

**Answer:**

Yes.

4. Because we are a fee-for-service contract institution, it would be difficult to bid competitively on a labor-cost-plus-fixed-cost/hour basis on unknown projects without a high risk of losing profitability—especially as we will be competing with an academic market, which has fewer costs associated. Is this the only option for you to outsource projects? We would like to understand if the NExT program will limit this collaboration.

**Answer:**

No, this is not the only route for sourcing work on a fee-for-service basis. But, in this renewal of the CBC, the preferred approach is to use the RFP process to evaluate proposals from a variety of organizations that can provide expert skills essential for drug discovery. Organizations selected to participate in the CBC will represent, we hope, all of the technical capabilities and capacities needed to carry out NCI discovery project work using any of various contractual mechanisms that are most appropriate for NCI, Leidos, and the site carrying out the work. Using this RFP process to identify qualified sites now should ensure that their skills can be enlisted more easily and quickly when the need arises for projects in the future. It is important to emphasize that the cost estimate worksheet required in the proposal is not a formal bid and no awards will result from its review. Instead, the worksheet serves as the basis for evaluating the reasonableness of the non-consumable costs proposed for each technical activity.

5. When is the reference questionnaire due? Would it be possible to include that date on the new Word form?

**Answer:**

Because it is part of Volume 1, the technical proposal, it is due at the same time, on November 5, 2015. It is your responsibility to ensure your references turn-in the questionnaire on time and to the correct Email address. Because the questionnaire is available as a Word document, you can add a due-date reminder to the copy that you distribute to your requested references.

6. In the Team and Key Personnel section, the solicitation asks for two or three examples of significant contributions and the *criteria that were used to judge performance*. Please give an example of the latter.

**Answer:**

If someone on your staff has a knack for greatly improving synthetic routes or the efficiency of difficult chemical coupling reactions, you might provide an example or two. Criteria here could be numerical improvements in yields, reduction in number of steps or cost of starting materials, elimination of expensive reagents, or insightful scientific strategy. Or perhaps a route improvement enabled the team to generate 100 analogs rather than 10 analogs in a month. Do not say simply that an individual is "a really good chemist."

7. In the Team and Key Personnel section, we list key personnel by name. For other personnel, we list the labor category and skill sets. Is that correct?

**Answer:**

Yes. The cost estimate worksheet template is available in an Excel file to facilitate this documentation.

8. Amendment 2, Answer to Question 2 states, “For each technical area proposal, offerors should show how each staff member would or would not be involved.” Should only the labor category be explained, or are you looking for details on each staff member? The example seems to suggest only the labor category.

**Answer:**

The revised cost estimate worksheet has a page where the expertise of each named person and the composite expertise of personnel available in each labor category should be indicated. For the labor categories that are not named but contain multiple FTEs, the worksheet prompts the offeror to indicate what number of the total available FTEs are available to work on the particular technical activity simultaneously.

9. It was stated in the last teleconference that six reviewer responses are allowed. Are centers also allowed to include additional letters of support to reinforce the proposal? For example, these may be from internal administrators to confirm some aspects of institutional support.

**Answer:**

Yes, these can be added to the proposal as an addendum.

10. Will Attachment 1 (cost estimate worksheet) be available in an Excel format or Word document format?

**Answer:**

Yes, one is already available and has been distributed as an Excel document via Amendment 2. The Cost Estimate Worksheet in Excel is also posted on the NExT website (<http://next.cancer.gov>). Offerors may also request the document at [cbcproposals@mail.nih.gov](mailto:cbcproposals@mail.nih.gov).

11. Will Attachment 2 of Volume 1 (offeror signatures) be available in a Word document?

**Answer:**

If you are unable to use Adobe to complete the necessary documents, please request the Microsoft Word document directly from [cbcproposals@mail.nih.gov](mailto:cbcproposals@mail.nih.gov).

12. Will Sections E, F, and G and the Certificate of Accounting and Billing System Adequacy included in Volume 2 be available in a Word document?

**Answer:**

If you are unable to use Adobe to complete the necessary documents, please request the Microsoft Word document directly from [cbcproposals@mail.nih.gov](mailto:cbcproposals@mail.nih.gov).

13. We, as two organizations, a university and a non-profit research institute, plan to submit a joint technical proposal in which each party has clear roles that synergize. As indicated in Question 26 of Amendment 2 our proposal will be accompanied by two cost estimate worksheets. Should two Volume 2 compliance (business) documents be provided as well?

**Answer:**

Yes, since the answers for the two organizations likely will be different.

14. Regarding the cost estimate worksheet, please clarify whether we should specify percent effort for named individuals as the percent effort that *can* be available for CBC participations or percent effort that *will* be committed to the CBC. The wording for this is different in the cost estimate worksheets, the Amendment 2 answers, and the RFP.

**Answer:**

For named individuals, indicate the maximum fraction of their time that could be made available to participate in the CBC. The Excel sheet has a section for documenting this, so you may wish to enter two separate lines for a site head, one for management/direction of the center and another for potential direct contributions to projects and project team activities.

15. The answer to Amendment 2, Question 14, is given as “no” but then says “references can be a current participant of the CBC.” Please clarify whether references for current CBC members can be a current participant of the CBC.

**Answer:**

The answer to Amendment 2, Question 14 should have been “yes”. References can be a current participant of the CBC. Offerors must choose references wisely to avoid any appearance of bias and to avoid any actual or perceived conflict of interest. An arm’s-length relationship is required to avoid conflict-of-interest situations. References cannot be Leidos Biomed employees or NCI employees. NIH employees may serve as references if they are not NCI employees.

16. The Amendment 2, Question 1 answer states that we need to address vertebrate animals in Volumes 1 and 2 of our proposals, yet the information required differs. Please elaborate on the appropriate level of detail for addressing vertebrate animals in Volume 1. For example, are you seeking a description of facilities, certifications, capabilities, or anticipated types of experiments? Should we follow the five points outlined in Volume 2 but provide less detail?

**Answer:**

The technical proposal section of Volume 1 should describe the capabilities and *in vivo* expertise being offered and the types of animal experiments that your center could perform. Facilities should be described in the Facilities and Equipment section. In Volume 1, it is sufficient to state

that your facility is fully accredited or qualified, then in Volume 2 include all required supporting documentation.

17. Does the vertebrate animals statement count in the page limit?

**Answer:**

No. The specific vertebrate animal statement is required in Volume 2.

18. The cost estimate worksheet provides space for fixed costs and provides a few examples. Are you also interested in seeing rates for interdepartmental charges for use of facilities and services such as spectroscopy, crystallography, and animal facilities?

**Answer:**

Yes, if they are required charges for using those capabilities that you are proposing to provide to the CBC.

19. May we group together the biosketches at the end of the document or should they be inserted following the Team and Key Personnel section?

**Answer:**

The biosketches should be grouped together at the end of the document.

20. Can we include a supplemental appendix in the technical proposal? For example, if we propose high-throughput screening, would an appendix of such work in the past 5 years be welcome?

**Answer:**

No. The technical approach must be self-contained within the 20-page limit. It is expected that Offeror's can summarize high-throughput screening experience within the 20 pages of the technical approach proposal. A large table showing all past runs is not necessary. However, the page limit within the Experience and Past Performance section is increased from the three (3) page limit noted in the RFP to five (5) pages (this is outside the 20-page limit noted above). Nevertheless, presenting catalogs or tables of large numbers of contracts and experiences is not desired. The idea is to support what has been proposed in the technical section. This might feature an illustrative example, showing significance, and a short list of contracts.

21. Should federal contracts alone be described?

**Answer:**

No, feel free to describe federal contracts as well as others.

22. Should we contrast different methodologies in high-throughput screening?

**Answer:**

If you believe your method is different or better than other traditional, or more common approaches to HTS, please explain those parameters in your proposal.

23. Regarding high-throughput screening, can we state the cost of this activity in the proposal on a fixed fee (e.g. per assay point) basis? (rather than FTE-based)

**Answer:**

That is fine, if you prefer it. Try to edit the Excel sheet that is provided to suit this purpose. Or if the version in the original RFP document is more suitable, use that form.

24. The first-tab spreadsheet for cost estimate doesn't seem to indicate the proposed percentage of effort to be considered. Is that intentional?

**Answer:**

That is intentional. The second tab of the Excel worksheet indicates the amount of time that can be committed by individual personnel or categories of scientific staff. We can put the fractions and costs together if the people are named. The first tab is not intended to show total cost for a fixed amount of work, but rather for us to estimate the overall reasonableness of conducting scientific work at your site. You cannot offer a full cost proposal now, because you do not know what projects you will be working on.

25. Will this RFP be presented again next year?

**Answer:**

No. The goal is to create a full consortium now that will be in operation for five (5) years. If you have something additional to offer the program down the road, you could speak to us at that time and we could consider it as a one-off situation.

26. The project seems to be matrix managed. Are you looking for both people who have facilities with high throughput capability and people with deep expertise?

**Answer:**

Yes

27. Could you describe the desired pathway within the program—the building and use of a team, taking a protein and moving it through a pipeline, etc.?

**Answer:**

This program functions as a pipeline from target validation to clinical trials. Submitted project applications will be vetted by an external group, and evaluated for either discovery or development projects. A team will be built. There will be milestones—the first likely will involve validation of data. Much of the process will be dependent on the center's expertise. Offeror's are encouraged to be familiar with the NExT Program and are referred to the NCI's website <http://next.cancer.gov/about/default.htm>.

28. Is there an estimate of the number of projects that will be supported?

**Answer:**

The website noted in Question 27 above has a lot of information about the program, including figures, showing the phases of the pipeline and the projects that are active at each stage. A budget figure for the program is not being shared.

29. What is the continuity of funding for a center? For example, could a participating center be activated for a year and then not used the next year?

**Answer:**

One goal is maintain a well-balanced portfolio. This process can involve new discovery projects entering the program and other projects falling out of the program.

30. We are late in assembling a team. Would it be possible to contact the program down the road to discuss our research activities and library of compounds (natural products)?

**Answer:**

Yes, contact the NCI. We can put you in touch with the people working on natural products at NCI and who maintain the repositories.

31. Will the submitted information on costs be kept confidential?

**Answer:**

Yes. The information will be kept confidential in perpetuity. Proposal reviewers will sign confidentiality agreements in advance of receiving the materials to review

32. If two universities apply as a single team, will they require two separate cost estimate worksheets?

**Answer:**

Yes. They likely will have different rates, fixed costs, accounting standards, etc. Offeror's will not need a consortium agreement immediately. All successful Offeror's receiving an award will sign consortium agreements. It is possible there would be subcontracts for each member of a close pair. Their relationship would be similar to the relationships between other members of the consortium.

33. If a center is applying to be specialized or dedicated or both, can one proposal be used?

**Answer:**

Yes. Be sure to indicate what type of proposal is being submitted—for consideration as specialized or dedicated or both.

34. If we have four deep wells of expertise, do we apply as specialized with those areas of expertise?

**Answer:**

Yes. Specialized in multiple categories. After completing the evaluation process and in response to NCI needs, a determination will be made whether the expertise your Center is offering is best suited to being a specialized or dedicated center. This categorization may be different from what you proposed in your response to the RFP, and also may be open to negotiation.

35. If an institution has a strong collaborator—e.g. a medical institution that does research—would we use duplicate budget forms, with explanations?

**Answer:**

Yes.

36. For a single center proposing in multiple specialized categories, is the page limitation for past performance five pages for each?

**Answer:**

No. The limitation for the past performance section would be five pages total for all the proposed activities, for example with five categories about one page each.

37. Is there an estimate of the number of runs of high throughput screening or number of assays that will be desired? We can do about 40 per year.

**Answer:**

We have 10 small molecule drug discovery projects today. We encourage you to encourage your colleagues to submit good applications for drug discovery projects, using the <http://next.cancer.gov> Website, which might then be selected for work in the NExT portfolio.

38. It was noted that we might list interdepartmental costs and rates on the Other Direct Costs worksheet. Must we annualize the costs (which can be difficult)?

**Answer:**

We desire to capture costs independent of the number of projects you are working on. However, some costs depend on the number of projects (e.g. crystallography). Perhaps you can quantize the cost somehow. If there are a number of types of costs or charges, it might be best for you to give some examples in cases where it is difficult to state an annual rate. We wish to see the costs of existing factors (e.g., taxes, square footage) and the costs of opening the door for business. Not every cost may be a rate cost. Indicate clearly what it is an absolute cost unit. Disclose cost factors that are clear, what kind of cost basis are built on, straight fee, monthly, yearly, etc.

39. Should animal facilities be noted in the Proposal?

**Answer:**

If you are proposing work with animal models, you should indicate whether your facilities have limitations, as in the ability to import animals or cell lines.

40. What is the process, (unlike the single-stage, yes or no grant process)?

**Answer:**

If your proposal is deemed unacceptable, that is the end. However, if your proposal scores well with the reviewers, there will be a second stage which can involve back-and-forth discussion to clarify points and details in the proposal. You also may be asked to participate in some of the technical categories described in your proposal, but not others depending on the needs of the consortium and the quality of the other proposals in that particular category.

41. Can you describe specific needs for the CBC?

**Answer:**

The RFP was intended to capture all categories and skill sets that would be needed for successful small molecule discovery. However, if you have additional relevant skill sets, please discuss them in your proposal.

42. Must the number of pages for the reviewer questionnaire be limited to 3 pages or, since we now have the Word template, may the questionnaire exceed 3 pages?

**Answer:**

The Past Performance Questionnaire can exceed the three (3) pages.

43. Is there a way to track how many references have been submitted to be sure we achieve the required number of responses?

**Answer:**

It is the Offeror's responsibility to track the number of references submitted.

44. Should the response be restricted to US based sites?

**Answer:**

This is a competitive solicitation open for both domestic and foreign entities.