Attachment 1 - Questions and Answers

1. Is it necessary to include information about vertebrate animal use in both Volume 1 and Volume 2, or is that duplicative?

Answer:

It is necessary to address vertebrate animals in both Volume 1 and Volume 2. There are different purposes for referring to the Vertebrate Animal use Sections (VAS) in the two volumes. Animal studies as part of the technical proposal will be reviewed in the Volume 1 proposal; the requirements for VAS in Volume 2 (Compliance) are different than what is required in Volume 1.

2. What is the approximate scale of resources that should be forecast in the cost proposal when considering an offering for Designated Center status under a Master Service Agreement (MSA)? For example, should offerors project costs for scientific and administrative resources for an approximate number of projects in the pipeline at any given time or anticipate more projects at steady state?

Answer:

Using the revised Cost Estimate Worksheet (attached), Offerors are to provide the median annual pay rate for all labor categories involved in any proposed activities. That would include key personnel, technical laboratory staff, infrastructure, and operational staff such as information technology (IT) support and database management. For Key Personnel--indicate total % time that this individual will be committed to CBC participation, and their area(s) of technical expertise.

For individual labor categories, indicate how many individuals (or FTEs) could be available to participate in the CBC and their area(s) of technical expertise. For each technical area proposed, offerors should show how each staff member would or would not be involved, selecting the particular activity for each person in a personnel matrix and specifying technical area competencies and expertise.

Proposals should not specify consumable costs, because they will scale with the defined work scope. Fixed costs should be specified and can include IT and computing resources, hardware infrastructure, and other costs required to conduct laboratory-based activities. Often these fixed costs are not obvious, and Offerors are encouraged to check their monthly charges from their institutions.

In order to incorporate these changes, Offerors should use the Cost Estimate Worksheet in Microsoft Excel. The Cost Estimate Worksheet will be posted on the NExT website (http://next.cancer.gov) and is attached to this amendment as a separate document.

3. Are the biosketches for the key personnel and other personnel included in the page limit for the team and key personnel section?

Answer:

Biosketches are not included in the page limit. Proposals should use the NIH standard format biosketch template, and it will not be counted against the page limit.

4. How many Dedicated Centers and Specialized Centers will there be?

Answer:

It is anticipated that between two to eight Dedicated Centers will be awarded as a result of this solicitation. The number of Specialized Centers will depend on the variety of specializations that are proposed.

It is up to Offerors to propose their specializations for such Centers. The goal of this solicitation is to award at least two centers per specialty in order to reach the capacity the CBC will need to run multiple projects simultaneously.

5. Should offerors submit a proposed cancer drug discovery project at the same time as a Center proposal or offering for the subcontract?

Answer:

No. Do not propose specific projects in the proposal; any future projects proposed are not relevant in the selection of Centers. The project work scope and work assignments will come as projects are received, approved, and accepted into the NExT program. It is not possible to be specific about projects to propose. However, past projects can be used in the proposal to document past performance and exemplify the type of work the offeror can perform related to the technical areas proposed.

6. Is there a limit to the number of key personnel who can be in the proposal?

Answer:

There is no limit to the number of key personnel. But the proposal should fully indicate how many will be involved in the particular technical areas proposed and their different roles or responsibilities. For example, if five key personnel are proposed, some might be involved in different technical activities under the RFP, but the principal investigator (PI) might be involved in each area.

The revised Cost Estimate Worksheet (included as separate Microsoft Excel file) has been developed in a manner to easily indicate which key personnel will be involved in each activity and provide a rationale of their roles and responsibilities for those technical areas. Do not overload proposals with senior personnel with unclear or duplicative roles.

Proposed personnel will be reviewed in order to see whom will be applied to CBC projects if the institution is named as a Designated or Specialized Center; not a list of excellent people working at the institution. It is important that the proposal not only mark personnel by category but also describe why they have been so marked, what their roles are, and what their responsibilities are. Their biosketch should demonstrate their expertise and qualifications.

7. What is the time period for costs on the cost estimate worksheet?

Answer:

The time period for labor rates and estimated fixed costs is one (1) year. Some proposals may cross fiscal years, and many in academic institutions might be crossing over a 12-month period when there is a raise or a cost-of-living adjustment. It is up to the individual site to decide how to indicate those raises or adjustments. Approaches include (a) submitting two Cost Estimate Worksheets – one for each fiscal year or (b) submitting a single Cost Estimate Worksheet containing two columns – one column for each fiscal year.

8. Will the cost estimate be reviewed for reasonableness?

Answer:

Yes, particularly as applied to how many people are proposed for a specific technical area. For example, as stated above, having five PI level staff all leading the same particular task would be considered unreasonable. Salary ranges tend to fall in line according to a person's level at the institution. Salary rates cannot exceed the Federal Government's Executive Salary Level II (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/EX.pdf).

9. How is percent effort determined?

Answer:

Percent of effort is not a factor in this proposal. Rather, annual labor cost plus fixed costs should be specified.

10. Is the cost estimate worksheet considered a binding cost proposal, or will there be a chance to provide a cost estimate for assigned work when it is assigned?

Answer:

No. The purpose of the Cost Estimate Worksheet in an offering that allows review of reasonableness, and it is actually a review of competitiveness with other sites for the specific technical areas. If an Offeror is selected and given work assignments, there will be a chance to estimate costs for the proposed assignment before entering into the agreement. Binding cost estimates will be solicited as project-based work is issued to the selected Centers.

11. Should institutions with two distinct centers come in as a single offering or as two distinct centers? Is there a preference to submit a single, unified response or separate responses for each center?

Answer:

If the two distinct centers have a current collaborative arrangement or envision having a collaborative arrangement, then the sponsor could choose to submit a single proposal. If they have operated separately in the past and intend to operate separately in the future, then the sponsor of the organization could choose to submit two separate proposals that clearly do not have overlapping technical areas, expertise, or track records. This depends on whether the two centers in the institution are fundamentally distinct or two elements of a larger program. Only the offeror knows that and can make the decision about whether the centers intend to collaborate under a single PI with a single means of governance and work assignment versus two standalone centers.

There is no right or wrong decision or preference for one or the other. It depends on what is reasonable and what makes the most sense in the context of institutional operations. Past performance is key and should be documented to support the proposal. The review of a proposal for a collaborative center that has never collaborated in the past is likely to go poorly.

12. Several prospective offerors referred to the "RFA" in their questions.

Answer:

The offering is an RFP, not a Request for Applications (RFA). An RFP is to generate a contractual basis for specific work and research and development services. It is not for grants. Offerors are asked to emphasize that point with their sponsored program or business offices.

Also, the review process for contract proposals is different from a grant. A grant application is accepted or rejected in one step according to its score. In this contract procurement process, Offerors with a competitive proposal will have an opportunity to respond to clarification questions, with responses incorporated into the SEG report and recommendations to NCI. It is not a one-and-done review; it is a dynamic process with a second step after the review. But a technically inferior proposal will not make it to that second step.

13. Should references be current or past collaborators or perhaps a mixture of both current and past?

Answer:

Choose references with the most detailed insights into past performance on projects who can speak to the quality and impact of those projects and their relevance to the scope of work outlined in the RFP. They could have been collaborators or consultants or even colleagues, past or present. The main thing is to choose people who can speak insightfully and with detail about the

offeror's past performance. They should know the work of the offeror and be able to write a detailed review.

14. For centers with previous experience within the CBC, can references currently be part of the Consortium, Leidos Biomed, or NCI?

Answer:

No. References can be a current part 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. Again, references cannot be Leidos Biomed employees or NCI employees. NIH employees may serve as references if they are not NCI employees.

15. Can references be internal to the bidding institution (e.g., a collaborating group within the institution) if not currently associated with the CBC?

Answer:

Yes. References can be employees of the bidding institution as long as they maintain an arm's-length relationship as independent collaborators with no supervisory or direct reporting relationship or potential to gain personally or professionally from a CBC award. They should be outside direct or indirect influence or control of the offeror. However, it is not recommended that all references come from the home institution; some references should be employees of external organizations. Offerors should consider the impression they would convey by using only internal references.

16. Is there a limit on the number of external questionnaires that can be requested and submitted as references? One might imagine different reviewers selected to highlight the different specific technical areas being proposed in the offer.

Answer:

This requirement is changed to require a minimum of three (3) but no more than six (6)references.

17. Are all NIH employees excluded as references or only NCI employees?

Answer:

Only NCI employees are excluded as references. NIH employees who are not NCI employees *would* be eligible.

18. Are references required to be at U.S. institutions?

Answer:

No. The only requirements are that they are qualified, have detailed knowledge, and can vouch for the offeror. Citizenship does not matter.

19. For a proposed Dedicated Center, will there be flexibility to apply dedicated personnel funding in different ways in order to best meet the needs of a given project?

Answer:

Yes. For example, a center might choose to reapply certain full-time employees or staff from chemistry resources toward drug metabolism and pharmacokinetics as a project progresses. The goal is to enlist multiple staff members for each of the technical areas proposed. The proposal should indicate which personnel are involved. It is expected that some staff members will be involved in more than one technical area. This will be easier to understand when the revised template for the matrix of the staff and proposed technical areas is available (see attachment). Part of the benefit of the MSA is the flexibility to propose which staff members will continue into the next phase of the project.

20. Can an institution propose both Dedicated and Specialized Centers?

Answer:

Yes. That is related to question 11, above, about whether to consolidate and bid a single center or submit proposals for two centers. That is an important decision that offerors must make relative to their organizations.

21. Will proposed centers that are not currently members of the CBC be scored in the same way as those that are currently part of the Consortium? That is, is there any advantage to being part of the Consortium?

Answer:

The scoring rubric of the review group will be the same for current CBC members and new Offerors not part of the CBC. It will be applied equally to all of the proposals. However, there is one important distinction. The past performance criteria of current CBC subcontractors will consider not only external references but also the subcontractor performance system used to review performance of the CBC subcontractors every six (6) months. For those who are not part of the current CBC, only the external reviews will be available.

22. Revisiting the questions about who can be references, may past performance questionnaires be submitted by an incumbent under the current contract?

Answer:

Leidos Biomed and NCI employees cannot be references. NIH employees who are not in NCI can be, and any nationality or citizenship is allowed as a reference.

23. Without a specific task as a basis for a detailed VAS, should generic animal capabilities and licensure or accreditation be provided?

Answer:

Offerors must complete the VAS required for Volume 1 and Volume 2; those are very important if using vertebrate animals. Offerors who are proposing any technical areas that would require animal use should complete the VAS for both volumes. Any proposal that contains animal use must include those sections.

24. Should a center that has developed methods that are highly successful for a particular technical application and enable very rapid use in different technical areas be a Dedicated Center or a Specialized Center? The expertise would be broadly applicable to many of the projects. It is a single technology or a single technical application.

Answer:

The method described could be considered a core service that contributes to multiple projects. It actually is not developmental in nature, but is a tool to advance projects from A to B, but itself does not advance from A to B. If the methods being offered are not commonly used at other institutions, but they are used frequently to support many project teams or project-focused activities, then one would understand this to be a Specialized Center, even though the Specialized Center would be used frequently by the project team. It would not have wide expertise addressing multiple technical project areas and could not necessarily handle direct discovery projects moving through the project stages on its own, but it would be a very frequent contributor to teams. That would be more appropriate as a Specialized Center.

25. For a biology project that includes protein structure visualization, but does not possess expertise in protein crystallography, can there be a Specialized Center that just proposes to analyze the crystallography data of another institution?

Answer:

Yes, that would be fine. If it is dependent on an upstream vendor to ship the material needed for the work, then this protein structure visualization work would be conducted by a Specialized Center.

26. Can a private organization and a public organization join forces to apply?

Answer:

Yes, if they have a clear relationship. One organization would be the lead organization. The offeror must be clear that the two organizations are coming in together as a joint enterprise and clearly specify the roles and responsibilities of the two organizations. Two cost estimate worksheets should be submitted, one for each of the organizations, and they should clearly delineate the

responsibilities of each person in each organization. There are no restrictions on the nature of the organizations that can respond; however, no second tier subcontracting is permitted in support of this effort. Please refer to Volume 2 – Compliance Documents Section F.1.

27. Would it be helpful to also include in the proposal potential partners who would be upstream members, or is that unnecessary?

Answer:

That depends on what is meant by potential partners. If they are other centers at the same institution, that was covered by question 11. If they are from a single institution, multiple skills can come from different departments or sectors. If partners or collaborators are from other institutions, separate proposals from different institutions are preferred. Being under the direct control of the offeror is different from having to be enticed to be a collaborator.

Another issue is past performance, which is key. If an institution proposes a partnership that has never been used before, it will not be convincing because it cannot show past performance. Speculating on a possible relationship that has not been demonstrated by past performance is somewhat delusional.

28. Is it true that the contract does not support technology development?

Answer:

Subcontracts resulting from this solicitation will not support technology development if that technology is only an idea on the blackboard but has never been started. But it will support optimizing, developing, and improving on technology if it is being used at the selected Dedicated or Specialized Center and is ready to be deployed to projects. It must be capable of supporting at least one stage of discovery and facilitating, enabling and accelerating that drug discovery.

29. Would the contract include go/no-go milestones that are performance-based?

Answer:

Yes, NExT projects are conducted with go/no-go milestones. Offerors should propose which technical stage of NExT discovery projects might be most relevant for the application of its technology and the situations in which contributors would most likely be made to the team's work. Offerors are referred to the NCI's website on the NExT Program (http://next.cancer.gov/about/default.htm).

30. If optimization of technology is necessary before it can be applied to drug discovery projects, could the offeror begin involvement at a later program point?

Answer:

Yes. Specialized Centers will be contributing to project teams at various points over time. If the portfolio of research projects needs a special technology at a certain time, then the Specialized Center(s) will be added to the team at that time.

31. Does the SEG have the possibility of looking at the Dedicated Center applications but deciding that it would actually choose that application as a Specialized Center with specialized capabilities?

Answer:

Yes. In the end, that decision will be made by members of the SEG and DCDT personnel.

32. Can an offeror be selected as a Specialized Center because of some special capability?

Answer:

Yes. Offerors should propose what they think they are best suited for. The evaluators will take the best offerings and assemble the best program so that the CBC can be a complete drug discovery program. The first step is for an institution to submit an Offer of the best center it can be, so that the Proposal is competitive at the level of the technical and scientific review by the SEG. After that, those selected Centers will be assembled into the Consortium by NCI. At the end of the process, NCI will decide, based on all the information from the SEG, how to place the different centers and what work will be assigned to them as either Dedicated or Specialized Centers.

33. The costing worksheet includes a line for indirect costs. Does the solicitation require a negotiated indirect cost rate? If yes, if an offeror does not currently have a negotiated indirect cost rate, should one be instituted or should it be negotiated at a later time? How does that work?

Answer:

Indirect rate agreements, either negotiated or provisional, are required for all cost reimbursement type subcontracts. When a provisional rate is used, the agreement will be modified accordingly once the rate is finalized. Other subcontract types such as Fixed Price or Time and Materials do not require the submission of a rate agreement. Current HHS-negotiated overhead rates (IDC, G&A, etc.) are acceptable. Organizations that do not have HHS-negotiated overhead rates can establish an overhead rate if selected.

34. If an Offeror is designated as a Dedicated Center, will work assignments proceed as in the past, that is, responding to statements of work (SOWs) that fit an institution's expertise?

Answer:

Yes, that is how work will be assigned under these MSAs. Work assignments would be SOWs. The NCI through Leidos Biomed could solicit proposed SOWs using a statement of objectives and have the centers propose SOWs, or it could issue SOWs and have the centers propose cost estimates to

do the work and modifications to improve it. The process is fairly flexible. It should be more streamlined and less cumbersome than Basic Ordering Agreements (BOAs).

35. If a Dedicated Center has a certain amount of ongoing support from the network, would there be an expectation that the center then would be engaged in ongoing activities?

Answer:

Dedicated Centers will earn funding through assigned project work from NCI; this would come from either NCI needs or as developed by the Consortium itself through the steering committee process. The work will be based on the portfolio, what the project needs are, and who has the capacity from the Dedicated Centers to support those activities. It is expected to be a fluid process that matches Dedicated Centers to the needed areas of expertise.

36. If a center has a preference for its research to be focused in certain areas, can that be specified in the proposal for the CBC to decide whether it wants a center to be focused in that certain area?

Answer:

Yes. A strong proposal will state how the offeror will use its technical expertise in ongoing work and the Proposal should clearly indicate the technical areas being proposed.

37. Expectations for references or bibliography for the technical section were not listed. Is that in separate pages or part of the page limit?

Answer:

Relevant scientific literature can be included in a bibliography, which will not count against the page limit.

38. Can a template for the letters of reference be provided? A formatted Word document that can be filled out on reviewers' computers would be useful.

Answer:

Yes, one is already available and has been distributed via Amendment No. 01. Everyone on the email distribution list received it, and it was also posted on the cancer.gov website. The Past Performance Questionnaire in Word is also posted on the NExT website (http://next.cancer.gov).

39. Is it possible to be more specific about what constitutes a Conflict of Interest (COI)? In study sections, often conflict of interest applies to someone an applicant has published with in the past, someone from the same institution, or collaborators.

Answer:

COI is defined as anything that would be perceived as affecting or influencing or impairing the judgment of someone about an offeror. A collaborator is not considered to necessarily have a

conflict of interest. What constitutes conflict of interest is influence over someone or any sort of quid quo pro or other arrangement that could benefit the reference if a good review is provided. A reference can be from the same institution as the offeror as long as there is not a direct reporting relationship. NCI wants an arm's-length relationship.

40. How can one be placed on the official mailing list?

Answer:

Communicate with Ms. Iman at cbcproposals@mail.nih.gov.

41. Will a reference be excluded if there is a determination of COI?

Answer:

Yes, but that should be unlikely because Offerors will avoid conflicts of interest in selecting references, even though selection of references is based on offerors' best judgment. References will be impacted by their credibility. NCI and Leidos Biomed are counting on offerors to be objective and select as references qualified people who know their work and can vouch for it with no vested interest and no possibility of benefit from a positive review.

42. Could applicant PIs who have worked on projects at centers be good references? It seems they would be, because they know how certain centers are working on their projects. But would it be considered a conflict of interest if their project is ongoing?

Answer:

They could be references if there is no benefit going back to the reviewer, no personal or professional gain, no monetary gain, nothing promised and no institutional pressure or loyalty to bias the review. It is also likely that an applicant PI who is an internal reference while being closely aligned with the investigators will be reviewed by the SEG as being biased or not entirely objective in his/her review. Hoping that a project would continue with the same center is not a conflict, because it is subject to a number of review levels. The aim is to avoid any situation in which someone is promised some sort of gain in exchange for writing a positive review, or the applicant PI writes a favorable review out of institutional loyalty. Offerors should use their judgment to avoid that.