RFP-NIH-NIAID-DMID-08-03

Amendment 1 (Questions and Answers, 3rd Posting)

This Amendment provides questions submitted by potential offerors and the responses provided by the NIAID. This Amendment will be updated as necessary to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment every two weeks to check for additional Questions &Answers.

"Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Diseases Other than AIDS"

Amendment Issue Date:	07/10/2006 (Questions 1 - 11) – 1st Posting 10/13/2006 (Questions 12 - 32) – 2nd Posting 11/09/2006 (Questions 33 - 50) – 3rd Posting
Proposal Due Date/Time: (UNCHANGED)	12/15/2006 at 3:00 P.M., EST
Issued By/Point of Contact: (UNCHANGED)	Teresa A. Baughman Contracting Officer OA/DEA/NIAID/NIH/DHHS 6700-B Rockledge Drive, Room 3214, Bethesda, Maryland 20892-7612 tb14j@nih.gov

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Offerors must acknowledge receipt of each posting of this Amendment 1, on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The hour and date specified for receipt of proposals HAS NOT been extended.

THE FOLLOWING PAGES PROVIDE ANSWERS CONCERNING INQUIRIES WE RECEIVED FOR THE ABOVE-NUMBERED SOLICITATION.

A CUTOFF DATE FOR QUESTIONS HAS BEEN SET AT 11/27/06.

Question 1: Will each VTEU be expected to perform inpatient challenge models?

Response 1: Each VTEU should have the capability and capacity for performance of inpatient investigational product administration and/or challenge studies. Attachment 4 of the RFP, "Statement of Work", discusses all of the clinical research facilities and resources (Section 10) required to perform this contract. Section 10.b. "Inpatient Clinical Research Facilities" specifically addresses inpatient facilities required.

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Question 2: Are there specific expectations for pharmacogenomics services, or is this design up to the offeror?

Response 2: This design is up to the offeror.

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Question 3: Are we permitted to contact EMMES (data coordinating center) or have access to understanding how data management is currently performed at the existing VTEUs?

Response 3: Detailed information on EMMES, as well as data management, is included in RFP Attachment 10, "DMID Funded Clinical Research Support Services Contracts", and Attachment 11, "Data Submission Requirements". In addition, offerors may visit the website for EMMES at www.EMMES.com .

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Question 4: Who holds the IND for the studies performed?

Response 4: DMID, NIAID holds the IND for studies performed at the VTEUs, except in special circumstances. Contractors will not be expected to hold the IND.

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Question 5: For subcontractors: Can we subcontract with a Veterans Administration (VA) site?

Response 5: There are no specific restrictions to prevent an offeror from subcontracting with a Government agency. However, there are special procedures that would need to be followed after contract award in order to implement any subcontract with a Government agency. Ultimately, offerors must determine what subcontracts to propose or not propose.

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Question 6: Are the proposals paper or electronic?

Response 6: Page 1 of the RFP states, "FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE". However, note that Attachment 1 of the RFP, "Packaging and Delivery of Proposal" requires the submission of both paper copies of the proposal, as well as CD-Rom.

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Question 7: Are many non-infectious disease vaccines (i.e. Tumor vaccines) anticipated to be tested during the next funding cycle?

Response 7: Most vaccines studied focus on the prevention of infectious diseases. Occasional therapeutic vaccines may be studied and wouldn't be more than one every two to three years. Attachment 7, Additional Business Proposal Instructions and Uniform Cost Assumptions is not changed as a result of this response. These types of protocols are already included in the estimate of protocols given for costing purposes in Attachment 7.

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Question 8: Budgeting for the full proposal and figuring out subcontractor costs is complex, it is helpful to have an estimate of FTEs, assays, etc given. The RFP notes to calculate 13.25 FTEs for budgeting purposes. Presumably, some of these FTE costs will be going to subcontractors as needed, or shall subcontractor costs, including salaries be calculated separately?

Response 8: The estimated 13.25 FTE support is for the prime Contractor only. Subcontractor costs, including subcontractor effort and direct labor costs, should be included in the subcontract line item category.

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Question 9: Will NIH/DMID entertain co-PIs for the VTEU responses, given that this is now being explored with grants?

Response 9: At this time there is only one (1) Principal Investigator allowed for contracts. Section L.2.b.(1)c) in the RFP states, "List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract."

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Question 10: Is it anticipated that any vaccine trials will be needed in neonates or premature infants?

Question 11: For budget calculations, how many inpatient trials (of any type) per year should be expected?

Response to Questions 10 and 11: Please refer to RFP Amendment 2 which addresses these two questions and provides new uniform cost assumptions.

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Question 12: For case study #2 which requires 2,500 subjects all enrolled within a month – do we assume that our VTEU (through use of subcontractors as needed) would be responsible for enrolling ALL 2,500 subjects? Or do we need to assume that all the VTEUs would be participating in this trial?

Question 13: Case study 2 asks for 2,500 volunteers in one month (Attachment 6, page 3). This exceeds the minimum number of adults for one entire year (1,200 adults per year, Attachment 4, page 2) that are expected per site. Are we to assume that all or several VTEUs and their subs will participate in case study 2 or are we to increase the number of subjects expected at this one VTEU plus our subs to a much, much, much larger number than the minimum specified?

Response to Questions 12 and 13: It is correct that case study #2 asks for 2,500 subjects. However, this and the other two case studies are only hypothetical case studies to be submitted by offerors for evaluation purposes only. It is not intended at this time for these case studies to be considered a part of the actual work that will be performed under this contract and should not be considered when using the number of participants/subjects provided for costing purposes in Attachment 7, Additional Business Proposal Instructions and Uniform Cost Assumptions. Each offeror should determine how best to propose conducting a case study such as this (i.e. with or without subcontractors). The case study states that the following should be provided in the protocol development plans, "Number of clinical trial sites and enrollment plans per site" and "Recruitment plans…including requirements for subcontracts".

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Question 14: Case study no. 3 deals with the development of a live, attenuated vaccine for meningitis. Is any further information available regarding this request? Specifically, whether DMID intends for this to be a bacterial form of meningitis or a viral form of meningitis, or whether DMID feels that this is not relevant to the response.

Response 14: The form of meningitis is not relevant to the response.

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Question 15: The 3 case studies ask for budgets including advertising (Attachment 6). Should we budget this as community education since the RFP instructions elsewhere say not to budget for advertising?

Question 16: Are recruitment costs for volunteers going to be allowed on this contract?

Response to 15 and 16: Yes, Attachment 6 does state that costs for advertising should be included in the Case Study Technical Cost Summary. However, the Statement of Work [section 3. Protocol Development, subparagraph a.4)f)2)] defines advertising costs as "advertising costs only as they relate to recruitment from existing patient population databases". Attachment 12, Proposed Advance Understandings goes on to clarify this issue when it states, "5. No costs for recruitment of participants outside of existing patient populations can be billed as a direct cost. These types of costs can be billed as part of indirect costs only." So, yes recruitment/advertising costs are allowed, but only within the parameters described in the RFP sections above.

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Question 17: A question regarding the 3 clinical trial protocols listed as part of the SOW for this response. In the Additional Technical Proposal Instructions (Attachment 6, page 2) under B. Protocol Development it states to 'Provide a scientific, technical and operational plan for the following two (2) clinical trial case studies'...yet 3 are listed....but in the Evaluation Factors Section M page 84 all 3 are listed. Are we required to include protocols for all 3?

Response 17: Yes, Attachment 6, Page 2 does state the following:

B. Protocol Development (SOW Item 3)
Provide a scientific, technical and operational plan for the following two (2) clinical trial case studies.

This statement is followed by two case studies. However, on Page 5 of Attachment 6, it goes on to state:

C. Additional VTEU Evaluations and Analyses (SOW Item 6)

This Case Study is suggested to be a total of 20 single-sided pages.
Case Study 3 ….

The first two case studies refer to the Statement of Work section on Protocol Development and the third case study refers to the Statement of Work section on Additional Evaluations and Analyses. There are three (3) case studies in all. So Section M correctly states that all three case studies will be evaluated.

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Question 18: Attachment #7 Gives specific business assumptions such as "number of Blood Specimens" for each year as well as how many and what kind of clinical trials per year. The question/clarification that I need is that in the "Technical application" the PI is asked to address 3 different cases and to provide a "Case Study Technical Cost Summary". All of these Cases appear to be adult studies and are outpatient studies. I need you to clarify that our Business Proposal should not be based on the 3 case studies and their budgets outlined in the Technical Proposal case studies. Should I assume then the Budget Proposal doesn't tie to the Technical Proposal but simply follows the Business Assumptions as well as other assumptions based on our own experience for these type of Clinical trial studies. In the previous VTEU application we were not given these type of Business Assumptions and the Technical proposal were not given Study Cases. We specifically tied the proposed Budget to the Technical application proposed studies. It appears with this new RFP that this is not the case? Please clarify.

Response 18: It is correct that the business proposal for the overall technical proposal is not tied to the case studies. The case studies are hypothetical case studies to be submitted by offerors for review purposes only. They are not intended at this time to be considered a part of the actual work that will be definitely performed under this contract and should not be considered when using the number of participants/subjects provided for costing purposes in Attachment 7, Additional Business Proposal Instructions and Uniform Cost Assumptions. As outlined in Attachment 6, Additional Technical Proposal Instructions, each case study should contain a “Case Study Technical Cost Summary” that pertains only to that case study. The overall business proposal should be based

on the uniform cost assumptions given in Attachment 7 for the overall contract as described in the Statement of Work, Attachment 4.

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Question 19: Study participant costs: Assume a total of $385,000 per year to defray costs (on Page 2 of Additional Business Proposal Instructions). Can you give me more detail as to what this $385,000 includes? Is this just the payment to the subjects participating in the trials (or does this include labs, etc)? If our case studies and other budgets total more than this, are we allowed to request the additional we feel is needed?

Response 19: **Costs for the case studies are not to be included as part of the business proposal**. See response to Question 18 above. Attachment 7 states: "Assume a total of $385,000 per year…to defray the costs incurred by subjects during participation in the clinical trial and clinical studies." These costs are to be considered participant reimbursement type costs (payment, gift cards, participant travel, etc.) It does not include other types of costs such as labs.

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Question 20: Clinical Specimens and Assays. A yearly amount for specimens and assays are listed to be performed. We just want to make sure that these are to be a part of the various protocols and not additional specimens/assays to be budgeted for other purposes.

Response 20: These specimens and assays are considered to be part of the protocols and not additional items.

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Question 21: Regarding the pediatric participants, we needed clarification concerning the 200 in the surveillance study. Are these participants to be taken from a completely separate pool or are they to be a part of the original 300 pediatric subjects.

Response 21: Attachment 7 of the RFP, Additional Business Proposal Instructions and Uniform Cost Assumptions, item 1.b. lists the requirement for the 300 pediatric subjects. Item 1.c. states that an additional study will be conducted with 200 pediatric subjects. Therefore, the 200 subjects are in addition to the 300 discussed in item 1.b.

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Question 22: Work scope item 1 asks for a minimal enrollment of 1,800 subjects per year, but also asks for the ability to provide for "rapid expansion" of enrollment. Does this mean that the request is for the contractor to be able to increase enrollment beyond 1,800 if needed, or for the contractor to rapidly expand to a ceiling of 1,800? If rapid expansion beyond 1,800 is being requested, will these additional numbers of subjects be anticipated to be healthy adults or other populations?

Response 22: The rapid expansion would be within the 1,800 subjects per year. It is assumed that the 1,800 subjects would be healthy individuals.

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Question 23: Regarding CVs: Do you also want the NIH Biosketches as well? Is there a particular format in which you want the requested CV's and if so, is there a link where we can access that information?, And do you want the eRA Commons User Names on the CV's?

Response 23: The RFP discusses requirements for resumes/CVs in two places. Section L.2.b.(1)c)(4) (page 50) states: "Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications." Attachment 6, Additional Technical Proposal Instructions" states in Section 6, "Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP." The RFP does not require any specific format, form or information as to how the resumes/CVs should be prepared. It is up to each offeror to decide how best to present the proposed staff's resumes/CVs. Regarding the eRA Commons information, the NIH eRA Commons is a web-based system for applicants and institutions to participate in the electronic grant administration process. This is a Request for Proposal (RFP) for contracts and therefore, the eRA Commons information is not applicable.

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Question 24: I have a question about the "pertinent contracts" section of the Business Proposal. It states in the RFP that "pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process". Does "related" mean related scientifically or related in terms of size of the contract?

Response 24: Section L.2.c.(9)d) of the RFP states the following (bolding added for clarification): "*Pertinent contracts* is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; **6) explanation of relevance of work to this RFP;** 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted." Although item 3) does request the contract dollar value, item 6) (noted in bold), asks for information on relevance of work to this RFP. Relevance to work could include either size, scope or both. Each offeror will need to determine whether or not one of their contracts is pertinent.

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Question 25: Cost or Pricing Data.....In past RFP submissions, the requirements have varied. On one of the proposals, we submitted catalog pages and POs for every single material line item. On the last proposal, the CO only wanted a full listing of every item. During negotiations, she required catalog pages and POs just on items over $1,000. Which method do you prefer?

Question 26: On Page # 71 section #4 "Requirements for Cost or Pricing Data or Information other than Cost & Price Data" can you explain what this section is saying? I know on the past VTEU application we had to have either Catalog or Quotes to back-up our pricing but these were not submitted as part of the application but once we got into Best & Final offer stages we were asked by the NIH to supply supporting documents on specific line items. Is this still the case or are you now wanting us to supply all back-up material with the application? Please Clarify.

Response to 25 and 26: Section L.2.c.(3) of the RFP discusses Information Other Than Cost or Pricing Data. This RFP does not require official, certified Cost or Pricing Data. This RFP Section lists various types of cost categories and the information that should be submitted with the business proposal. It states that a listing of costs in these categories (supplies, other direct costs, etc.) should be provided, along with a basis for pricing (for example 35 items @ $.50 per item, etc.) If the cost category is equipment, then three (3) vendor quotes should be provided. If the Government determines that negotiations are necessary and your proposal is considered to be in the competitive range, some additional supporting documentation may be required at that time. However, it is not anticipated that such documentation will be required on every single line item.

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Question 27: Attachment #13 – I assume this form should be simply attached to the end of the SBA plan?

Response 27: Attachment #13 is the Small Disadvantaged Business (SDB) Participation Plan and is a completely different requirement than the Small Business Subcontracting Plan. Please complete both forms and include them in your business proposal as separate documents, not combined.

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Question 28: On Attachment #1 Page #2 can you clarify the Statement "Offerors Must Certify that the information in the paper & electronic copies is exactly the same"? Should this be in the cover letters that we send in with both Technical & Business proposals?

Response 28: Yes, the certification should be included on the cover/title page of both the hard copy, as well as in the electronic version.

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Question 29: We have potential subcontracts who may be submitting a proposal from their own institution, but are willing to go in on our proposal as a subsite. Is it okay for a subcontractor on our proposal to also have submitted their own proposal? And also we have one subcontractor who is willing to be a subcontractor for us

and another site submitting a VTEU proposal. Are there any restrictions on sites being involved in multiple proposals or being subcontracts on more than one proposal?

Response 29: Each offeror/subcontractor needs to best determine how they will propose for this RFP and how they would handle these various proposal arrangements. If an offeror is proposed on more than one proposal, they must consider and address how they will deal with any personnel and resources overlap in the event more than one proposal they are listed on is selected for award.

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Question 30: Would it be allowable for us to budget a small percent of personnel effort as core support for a subcontractor site? They have been partners with our VTEU on numerous studies and are requesting ongoing support as part of our contract proposal. Would this be a reasonable cost on an ongoing basis, or would we have to contract with them separately for each study as we are doing now?

Response 30: Each offeror has to decide how best to present their capabilities and how to cost out their business proposal based on how they propose to do the work outlined in the Statement of Work, Attachment 4. The business proposal should include costs based on how an offeror proposes to perform the work, and also in accordance with the uniform cost assumptions included in Attachment 7. If an offeror proposes to have a subcontractor perform portions of the Statement of Work, then that should be included in the cost proposal.

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Question 31: Work scope item 1 states that enrollment may be done at "affiliated clinical sites", while workscope item 2 requires the contractor to "solicit, evaluate, and award" subcontracts when necessary. The comment is made that such subcontracts must be approved by the contract officer before initiation of studies. It is unclear whether "affiliated clinical sites" that might be part of the submission would also need to be approved by the contract officer, or whether the two SOW items are calling for two different activities: (1) establishment of affiliated clinical sites, and (2) establishment of a process to solicit additional subcontracts as needed.

Response 31: Item 2 of the Statement of Work defines "Affiliated sites" as subcontractors. Any affiliated sites/subcontractors that are proposed as part of accomplishing the Statement of Work (Attachment 4) should be discussed in the technical and business proposals. All subcontractors, whether a part of the initial proposal submission or proposed later after a contract is awarded, will require prior written approval of the Contracting Officer prior to protocol implementation. These are not two different activities.

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Question 32: Work scope item 5 deals with safety oversight of clinical trials. Among other things, it requests that the contractor develop a "system of records" for each clinical study undertaken. It is not clear what is meant by this request. Currently, development of case report forms (CRF) is the responsibility of the Data Coordinating Center (DCC). Is the intention to shift this activity to the individual clinical contractors (this seems unlikely, particularly for multicenter studies). If not, then what type of "system of records" other than CRFs is being requested?

Response 32: Section J of the RFP, Information Attachments, includes the applicable Privacy Act System of Records for this RFP. It is located at: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm This document discusses the categories of individuals covered, the categories of records covered, and the policies and practices for storing, retrieving, accessing, retaining, and disposing of records in this system. The Privacy Act System of Records is the same one included in all existing VTEU contracts. For this RFP, it covers items such as records stored within the clinical areas, off-site long term storage of records, who has access to these records, etc.

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Question 33: For the case study: We've have been assuming that when they say a live attenuated vaccine (MENA) against meningitis, they mean meningococcus serogroup A, and when they say MENB, they mean meningococcus serogroup B. Correct?

Response 33: Refer to Question 14 above and its response.

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Question 34: We had a few questions regarding Question 14 and its response. For case study 3, if the form of meningitis is not relevant to the response, does this mean that the protocol should be based on a generic "meningitis vaccine", without specification of a target organism, or that the applicant should choose a specific targeted infectious agent and develop the protocol on that basis? If the former, we wondered how we should develop the background section, define inclusion/exclusion criteria, select vaccine dose, define relevant safety outcomes, and choose laboratory parameters, since these factors are usually based at least in part on considerations related to a specific organism. As a related question, for all three case studies, are we to select vaccine candidates that are currently in preclinical or clinical testing, or are the vaccine candidates to be hypothetical formulations? If the later, should we also provide hypothetical data in the background and rationale sections to justify clinical testing of the vaccine candidates.

Response 34: See response to questions 12 and 13 above, which states that the case studies are hypothetical. The case studies should therefore be based on certain assumptions developed by the offeror for each case study. These assumptions should be delineated at the beginning of each case study.

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Question 35: We have read the revised Amendment 1 dated 10/13/2006. However, we still have differing interpretations here on Case Study #2. One interpretation is that we need to budget this case study for the full 2,500 here at our organization with other subcontracts as needed. The second interpretation is that we assume 2,500 to be done as a multi-center trial with multiple VTEUs. With that being the case, then we would budget for the number we would anticipate doing here at our organization with subs and the balance would be done at other VTEUs. If this is the case, how do we attempt to budget for the other VTEUs to come up with a total cost.

Response 35: See response to questions 12 and 13 above. In addition, it is not intended that this hypothetical case study be conducted with multiple VTEUs.

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Question 36: RFP Attachment 7 states $385,000 for "Study Participants Cost", so should we simply put this amount in as a single line item or do we have to breakdown this amount?

Response 36: Attachment 7, Additional Business Proposal Instructions and Uniform Cost Assumptions doesn't require a breakout of the amount for Study Participant Costs, so one is not needed.

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Question 37: The recent Q &A was helpful but we have an additional question concerning the development of the budget. We know we are to use the Excel spreadsheet supplied by the NIH to develop the budget . You have clearly defined the type and number of clinical trials that we should develop the budget. Based on that we have a question concerning the budget structure: Do you want to be able to differentiate expenses to each specific clinical trial or just combine all of the expenses.

Response 37: That is correct, the RFP did not request that the clinical trials (the ones discussed in the uniform cost assumptions in Attachment 7) be broken out in the overall budget. One consolidated budget is all the RFP requires.

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Question 38: When preparing the Business Proposal based on the 5 protocols required, do we assume correctly that there should be a summary with the total for all 5 protocols and then each protocol budget will follow with detail? Also, are we to include "core" personnel such as the PI, administrative, etc. in each protocol, or is it acceptable to have a "core" budget in addition to the 5 protocols.

Response 38: As discussed in the response to question 37 above, the instructions do not require a separate budget for each protocol. The number of protocols to use for budgeting purposes was to aid offerors in establishing their annual proposed costs overall.

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Question 39: The RFP amendments note that we should assume inpatient studies will be conducted in years 2, 4, and 6. However, we don't see any reference to how many inpatient subjects we should assume. In addition, how long the subjects are expected to be inpatients is also critical to determining costs. How long should we assume each subject's inpatient stay will be?

Response 39: Please refer to Amendment Three (03) which revises the uniform cost assumptions in Attachment 7 to address these issues.

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Question 40: Can/should we increase the 13.25 estimated number of FTEs in the years with inpatient studies?

Response 40: Section L.1.d. of the RFP states that the 13.25 full-time equivalents (FTEs) annually is "furnished for the offeror's information only and is not to be considered restrictive for proposal purposes". The 13.25 annual FTEs is the approximate amount of effort the Government considers required for each year, which included the inpatient studies stated in Attachment 7.

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Question 41: Regarding the two additional assumptions in Amendment 2 - Are these assumptions to be taken exactly or are these a minimum requirement, whereas we could propose more trials per year, etc. For example, is it acceptable to propose an inpatient trial every year (rather than every other year)?

Response 41: These uniform cost assumptions are to be taken exactly. Since we don't know at this time how many protocols and of what type (inpatient vs. outpatient) will be conducted under a resultant contract, the uniform cost assumptions were developed so that all offerors would be proposing on the same information. However, see the response to Question 44 below regarding "Alternate Proposals".

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Question 42: Are fixed price subcontractors OK?

Response 42: There is no restriction in the RFP as to the type of subcontracts that can be proposed.

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Question 43: We read the RFP to say that we need to submit the Small Business Subcontracting Plan with our proposal. It goes on to say that anticipated minimum goals for this RFP are:
30% Small Business
11% Small, Disadv Business
5% Women-Owned Small Business
3% HUBZone Small Business
3% Veteran-Owned Small Business

Is this passed down to our subcontractors as well, in that they need to submit a plan (if their total amount is over $500k). If so, do the anticipated minimum goals apply for their plan as well?

Response 43: Item 5. of the subcontracting plan discusses what needs to flow down to subcontractors. It states that the subcontractors do have to "adopt and comply with a plan similar to the plan required by FAR 52.219-9", which is the plan each offeror has to complete. The only difference is that the subcontractor's plan would go to the offeror and not be included in the proposal. It would be reasonable to assume that the subcontractors would need to try to project goals in line with the HHS's goals, the same as the prime contractor. The goals you reference have been increased and are included in the November 2005 version of the plan found at the website link shown in Amendment Two (02) of the RFP (http://rcb.cancer.gov/rcb-internet/forms/forms.htm).

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Question 44: We may propose a subcontractor that has an international site that can be used as a resource for recruitment. This international site is not a part of one of the specified RFP clinical trials or surveillance study and therefore will not be a portion of the subcontractor's required budget. Is it allowable to add this additional budget piece for a concept that would likely be proposed if the contract is awarded? If this is not acceptable to be included in the proposal and we were to be awarded the contract, would a supplement for this additional international expense be a possible solution to the extra expense?

Response 44: Section L.2.a.(5) of the RFP discusses "Alternate Proposals", which are proposals that deviate from the requirements specified in the RFP. Note that if an alternate proposal is submitted, an offeror must also submit a proposal for the performance of the work as specified in the Statement of Work and RFP. No additional "supplements" would be given after award of any resultant contract for work not included in the proposal.

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Question 45: We would like to know if you expect an offeror to have several subcontractors, especially to enhance enrollment. We may not propose subcontracts and just be prepared to expand enrollment. We would only mention in the narrative our arrangements on an as needed basis with national and international sites. Therefore, we are not listing them as subcontracted sites in the application. Is this is a correct interpretation of the RFP?

Response 45: There is no requirement in the RFP to have or not have subcontractor(s). Each offeror has to decide how best to respond to the RFP in order to accomplish the tasks set forth in the Statement of Work. Note that Section L.2.c.(11) requires a letter of commitment from any proposed subcontractor/affiliated site. In addition, Attachment 6, Additional Technical Proposal Instructions, Section 2, outlines the information an offeror should include in their proposal regarding any proposed subcontractors.

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Question 46: Could you please clarify how we need to acknowledge receipt of the amendments? Our understanding is that we provide a copy of them with each proposal submitted. If this is correct do we add this to the table of contents? What section?

Response 46: The business proposal attachment titled, "Proposal Summary and Data Record, NIH-2043" (see Section J of the RFP for link to form) includes a section for the offeror to complete regarding acknowledging Amendments.

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Question 47: We have a question about labeling of the "CDs". We know the naming of the electronic files is clearly outlined but as far as labeling both the Technical & Business "CDs" what information do you want on the labels? The info that is on the paper cover sheet? For the technical that wouldn't be a problem but we are not sure that all of the information requested on the Business paper cover sheet will fit on to a CD label. Please let me know how the CDs should be labeled for both the Technical & Business" parts.

Response 47: The CD label should contain the offeror's name, the RFP number, and whether or not the CD contains the technical or business proposal.

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Question 48: What size type/font should we use for this proposal? I assume the standard Arial 11 pt?

Response 48: Refer to Attachment 1 of the RFP, Packaging and Delivery of the Proposal, for proposal preparation instructions regarding formatting and layout.

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Question 49: We have a question regarding human subjects. Pages 51 indicates that there should be a section concerning this in the proposal; however, the template which we must follow as outlined in Attachment 6 does not include this category

Response 49: Attachment 6 of the RFP, Additional Technical Proposal Instructions, states that "the information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions of Section L of the solicitation, including information requested in this appendix (Attachment)". Although there isn't a specific section designated in the guidelines presented in Attachment 6, each offeror should address the human subjects information required in Section L (page 51) in the section they feel is appropriate or if needed, create a separate section in the technical proposal to address this issue.

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Question 50: Is there a cutoff date for questions?

Response 50: Yes, **the cutoff date for questions has been set at November 27, 2006.**