Request for Proposals Under RFP: NHLBI-HB-04-16

Retrovirus Epidemiology Donor Study-II (REDS-II), Coordinating Center

Request for Proposals: NHLBI-HB-04-16

Amendment Number: 02 (Two)

Issue Date: September 17, 2003

Issued by: Joann Ciufolo, Contracting Officer
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Purchase Authority: 42USC201, Public Health Service Act of 1944, as amended

Just In Time: Yes, See Section L, Instructions, Conditions and Notices to Offerors, Item 5

Small Business Set-Aside: No; NAICS 54170
Proposal Intent Due Date: September 2, 2003

Proposal Due Date: **October 22, 2003, 4:30 PM (Eastern Daylight Savings Time)**
. . . . . ***Changed*** . . . . . .

Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

1. By acknowledging receipt of this amendment on each copy of the offer submitted; or

2. By separate letter, telegram, or Electronic Mail which includes a reference to the solicitation and amendment numbers.

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.

The purpose of this amendment to RFP NHLBI-HB-04-16, is to (1) revise the due date for receipt of proposals, (2) change the contract award date, (3) revise the Draft Study Protocol (Exhibit 1), and (4) provide NHLBI responses to questions from potential offerors (a through j).

(1) The due date for Proposals is extended 7 days to **October 22, 2003**, at 4:30 PM (Eastern Daylight Savings Time).

(2) Section L, Item 11: Type of Contract and Number of Awards, Paragraph 1 is revised to **change the award date from August 1, 2004 to September 1, 2004.**

(3) RFP: NHLBI-HB-04-16, Exhibit 1: entitled Protocol for Solicitation Purposes, dated June 2003, (last item in Section 2. DESCRIPTIONS AND STATEMENT OF WORK FOR SOLICITATION PURPOSES) is revised. For clarification purposes, Part III. Draft Study Protocol (beginning on Page 4 and ending on Page 7) is deleted in its entirety. The deleted Draft Study Protocol was included as a sample study, but may be misinterpreted as the actual protocol. The studies to be performed in REDS-II will be developed by the Study Steering Committee after the award of contract awards.

(4) The following questions and responses are provided as clarification for RFP: NHLBI-HB-04-16:

Question a. SOW, Paragraph 15 calls for developing, updating, and implementing an approved Automated Information System Security Plan (AISSP). However, in Section L., Part III., Item 53 (b) we are uncertain if with the delivery of our proposal a detailed outline is expected as indicated in that particular section, or is all of this pertinent to the "successful offeror" as indicated in Item 53 (a). If the outline is to be included with our proposal submission, does this count against our page limit in either the technical plan or the appendices?

Response: Section L., Part III., Item 53, Paragraph (b) requires that a detailed AISSP outline be included in the proposal submission. This AISSP outline is an exception (other considerations) to the page limit requirements. Exceptions are listed in the RFP, Part 11. SECTION L. Instructions, Conditions and Notices to Offerors - Specific to this RFP, I. General Information, Immediately following Item 20., GENERAL INSTRUCTIONS "Page and formatting limitations."

Section L., Part III., Item 53, Paragraph (a) states that the "successful offeror" will be required by the to be awarded contract Statement of Work to develop or access a Federal Automated Information System (AIS). The "Sensitivity and Security Level Designations" are stated in Paragraph (a).

Question b: Will each participating Blood Center need to have the facility to hold up to 20,000 specimens per year including the freezers and the space for the freezers?

Response: No. Blood Centers must have standard laboratory equipment including a -20 C freezer and a -70 C freezer. The amount of freezer space needed for this contract will depend upon the research studies decided upon by the Steering Committee. Specimens will most likely be shipped periodically to the Central Laboratory or the NHLBI Biological Specimen Repository. There is no plan to a establish a large repository of specimens in REDS-II.

Question c: The procedures for the proposal should be "detailed". Here does it mean step by step instructions/descriptions as in an actual instruction for the use of a data entry program, or a detailed outline might be adequate? It might be more practical to prepare a step by step instruction after a study protocol is finalized.

Response: The RFP does not call for step by step operational procedures. Rather, you should provide sufficient detail to demonstrate that you understand protocol development, operational manual development, data entry, data management, data analysis and other tasks specified in the RFP.

Question d: Several potential options or approaches could be proposed to accomplish the objectives of the study. Does NHLBI prefer one approach to be proposed and consequently detailed procedures to be described based on that approach? Or does NHLBI prefer alternative options or approaches to be proposed? If the latter, should the procedures for one of the options be described or should procedures for all of the proposed options be described?

Response: The NHLBI does not have a preferred approach for accomplishing the Statement of Work. It is incumbent upon the offeror to propose the best approach to satisfy the objectives of the study.

Question e: Assuming participating Blood Centers will be different in many aspects, does NHLBI prefer a prescribed method for all centers to follow, meaning a set of exact procedures everywhere, or a proposal that will try to accommodate differences among blood centers as long as the quality of the study is maintained and the objectives are met?

Response: While there are likely to be differences among the blood centers participating in REDS-II, each center will be required to follow standardized study protocols. Any differences that might affect conduct of the study will have to be resolved during protocol development and prior to initiation of the study.

Question f: Since this study is a continuation of an existing project, will a proposal be judged heavily on the proposed detailed procedures rather than the strength a new bidder may have to offer to improve the performance on the existing practice, it might not be the best for the REDS II project.

Response: REDS-II is not a continuation of the ongoing REDS program. It is an entirely new program. Strengths and weakness of offerors will be determined during technical evaluation of the proposal. The technical review group will adhere to the technical evaluation criteria listed in the RFP.

Question g: Can laboratories with whom we currently collaborate be used for testing?

Response: A REDS-II central laboratory will be solicited under a separate RFP. Since any protocol that is proposed should be accomplished in a multi-center format, special testing (other than standard blood center testing) will be conducted by the central laboratory.

Question h. Are resumes included in either of the page limits set forth?

Refer to Part 11. SECTION L. Instructions, Conditions and Notices to Offerors - Specific to this RFP, I. General Information, Immediately following Item 20., GENERAL INSTRUCTIONS (revised by replacement of boiler plate language), page 2 of 7.

Response: No, resumes are not included in the Technical Proposal page limit. Personnel is listed as an exception.

Question i. Is access to the Code of Federal Regulations needed, or is certifying that the institution has such a policy acceptable? Is it necessary to submit the policy? We have been unable to find the 42CFR Part 50 Subpart F or 45CFR Part 94 at the CFR website.

Refer to Part 11. SECTION L, INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS, II. GENERAL INSTRUCTIONS, Item 38 entitled: Institutional Responsibility Regarding Conflicting Interests of Investigators.

Response: The Code of Federal Regulations citation is provided as a resource for offerors to obtain information regarding the requirement for institutional policies on conflict of financial interest. A searchable version of the Code of Federal Regulations (CFR) 45CFR Part 94 is located at the following URL:

http://www.access.gpo.gov/nara/cfr/waisidx_02/45cfr94_02.html

A Certification of Institutional Policy on Conflict of Financial Interest is included in the Representations and Certifications (RFP Part 10. entitled: PART IV - SECTION K Representations, Certification, and Other Statements to Offerors or Quoters (Negotiated) Item 27.). Submission of Representations and Certifications as part of the proposal is a requirement.

Question j. What periods of time should be used for cost proposals - by year or by study phase?

Response: Costs should be proposed by phase. That is:

Phase 1 - September 1, 2004 to May 31, 2005 - nine months

Phase 2 - June 1, 2005 to August 31, 2005 - three months
September 1, 2005 to August 31, 2006 - twelve months
September 1, 2006 to August 31, 2007 - twelve months
September 1, 2007 to August 31, 2008 - twelve months
September 1, 2008 to February 28, 2009 - six months

Phase 3 - March 1, 2009 to August 31, 2009 - six months