***Request for Proposals Under RFP: NHLBI-HB-04-07***

***Retrovirus Epidemiology Donor Study-II (REDS-II), Blood Center***

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| **Request for Proposals**: | NHLBI-HB-04-07 |
| **Amendment Number**: | 01 (One) |
| **Issue Date**: | September 17, 2003 |
| **Issued by**: | Joann Ciufolo, Contracting Officer<br>NIH/NHLBI, Contracts Operations Branch<br>6701 ROCKLEDGE DR MSC 7902<br>BETHESDA MD 20892-7902 |
| **Telephone Number**:<br>**FAX Number**:<br>**E-Mail**: | 301-435-0359<br>308-480-3432<br>ciufoloj@nih.gov |
| **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**:<br>**Proposal Intent Due Date**: | No; NAICS 54170<br>September 2, 2003 |
| **Proposal Due Date**: | **October 22, 2003, 4:30 PM (Eastern Daylight Savings Time)**<br>**. . . . . .*Changed*. . . . . .** |

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**Offerors must acknowledge receipt of the amendment prior to the proposal due 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-04-07, is to (1) revise the Proposal Due Date, (2) change the contract award date, (3) modify the Statement of Work, (4) revise the Draft

Study Protocol (Exhibit 1), (5) revise requested documentation in RFP Part 2. Article C.1. Statement of Work, e. Proposals should include the following information: 2., and (6) provide NHLBI responses to questions (a. through k.) from potential offerors.

(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-04-07, Part 2. DESCRIPTIONS AND STATEMENT OF WORK FOR SOLICITATION PURPOSES, ARTICLE C.1. STATEMENT OF WORK, Paragraph a., Subparagraph 1. is revised to **delete** the second sentence.

(4) RFP: NHLBI-HB-04-07, Part 2. DESCRIPTIONS AND STATEMENT OF WORK FOR SOLICITATION PURPOSES, Exhibit 1 entitled: Protocol for Solicitation Purposes, dated June 2003, is revised to delete Section III. Draft Study Protocol (beginning on Page 4 and ending on Page 7). 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 contracts in Phase 1.

(5) RFP, Part 2. DESCRIPTIONS AND STATEMENT OF WORK FOR SOLICITATION PURPOSES, ARTICLE C.1. STATEMENT OF WORK, e. Proposals should include the following information: 2. is revised to read as follows: "2. Document the experience and successful performance in the operation of a blood center participating in multi-center, long term collaborative seroepidemiology research studies."

(6) The following questions and responses are provided as clarifications for RFP: NHLBI-HB-04-07.

**Question a**: Is NHLBI interested in a larger number of donors screened or does 20,000 donors represent the real target? If a collection facility wants to implement the REDS study in only a portion of the donor base, what would be the optimal total number?

Response: The NHLBI is interested in obtaining donation data from a large number of donors. The 20,000 figure is a floor and not a ceiling for actual studies to be performed. Examples of the types of studies are included in RFP: NHLBI-HB-04-07, Part 2. DESCRIPTIONS AND STATEMENT OF WORK FOR SOLICITATION PURPOSES, Exhibit 1: entitled Protocol for Solicitation Purposes. Investigators are also encouraged to propose their own innovative approaches to studies. The number of donors for a particular study will depend on the study itself and the power that is needed to obtain statistically valid data. There is no optimal number for specific studies being proposed. Blood centers should keep in mind, however, that REDS II studies are multicenter studies, and sample size requirements for

statistical power will usually be accomplished by taking a sample of subjects from each participating REDS-II blood center.

**Question b:** Can a donor subset be chosen from the region on operational grounds (proximity to the blood center for follow-up for example) or to represent a geographic area of interest, rather than planning representative sampling among all donors in the region?

Response: Taking into account all of the requirements of the RFP, Section M - Evaluation Criteria, offerors are free to choose a subset of donors from a region on operational grounds or to represent a geographic area of interest.

**Question c:** 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 d**: Should proposed research projects be written to represent how we would proceed in our region, or written only as a multi-center project (with as yet unnamed blood centers) omitting any local specificity?

Response: Research studies included in proposals may be written specifically for the blood center with which the offeror is affiliated. Proposed studies must have the potential to be translated to the REDS-II blood center multi-center format and represent research opportunities relevant to transfusion safety and/or availability of the U. S. blood supply. Proposed research studies are for evaluation purposes, and will be used for source selection purposes. As stated in the RFP, the REDS-II Final Protocol (including studies to be performed) will be developed by the REDS-II Steering Committee during Phase 1 of the Study.

Proposed studies should be compatible with the direct labor delineated in the staffing guidelines provided in the RFP, Part 2. ARTICLE C.1. STATEMENT OF WORK, Paragraph e. Level of Effort. They should include, for example, specific methods of data collection, ways of contacting donors or methods to be used for donor/recipient follow ups, etc. The intent of this acquisition is to award six to eight REDS-II blood center contracts.

**Question e**: RFP, Part 2. DESCRIPTIONS AND STATEMENT OF WORK FOR SOLICITATION PURPOSES, ARTICLE C.1. STATEMENT OF WORK, Paragraph e. 2. states that offerors are to "Document the experience of the proposed personnel in the administration and management of multi-center epidemiology programs." Is this meant for the Coordinating Center? Or, alternatively, are we to describe our experience in participation in multi-center

trials and our local region's management/administrative ability to meet the requirements of multi-center studies?

Response: See (5) above which revises the requested documentation as follows: "2. Document the experience and successful performance in the operation of a blood center participating in multi-center, long term collaborative seroepidemiology research studies."

**Question f**: 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 g**: 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 h.** 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 offeror may have to improve the performance on the existing practice?

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 Section M of the RFP.

**Question i**. 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 j**. 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 k**. 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