"HUMAN GENETIC RESOURCE CENTER: DNA AND CELL LINE REPOSITORY"

AMENDMENT OF SOLICITATION NO.: <u>RFP-NIH-NINDS-02-03</u>

AMENDMENT NO.: 01

EFFECTIVE DATE: April 23, 2002

ISSUED BY:

National Institutes of Health National Institute of Neurological Disorders and Stroke Contracts Management Branch, DER Neuroscience Center, MSC 9531 6001 Executive Boulevard, Suite 3287 Bethesda, Maryland 20892-9531

Point of Contact: Patricia S. Denney, Contracting Officer

NAME AND ADDRESS OF CONTRACTOR: To All Offerors

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of Offers remains unchanged, May 6, 2002, 4:30 P.M. (local time). Offers must acknowledge receipt of this amendment on each copy of the offer submitted, or on the PROPOSAL SUMMARY AND DATA RECORD, ATTACHMENT #5, OF THE SOLICITATION.. FAILURE OF YOUR ACKNOWLEDGEMENT 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. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

All other terms and conditions of the RFP remain unchanged.

DESCRIPTION OF AMENDMENT (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Purpose: To include responses to technical questions submitted by potential offerors, and to provide a Proposal Checklist to assist in submission of technical and business proposals.

Technical Questions and Responses

The following are responses to formal questions submitted by potential offerors.

Question #1 – There is some confusion by the statements in ARTICLEC.4. SPECIAL REQUIREMENTS, paragraph 1., Subject Confidentiality, on page 6.. It states that all data to be placed in this bank to be totally unidentifiable. That is, as they come into the bank all information on the individual is removed. This is in direct conflict with the list of technical points on page 42, especially number 4 and 5. Can you clarify this apparent conflict?

Answer #1 -These statements are not in contradiction. In fact, they make the same statement. Identifiers are to be used in terms of a number for the individual, and a number for the kindred. The contractor will not know the names, social security numbers, or other PERSONAL identifiers of the individuals on whom samples are collected. Relationships between individuals included will be noted using the masking system of pedigree and individual number. Hence the information will be masked, but not anonymous.

Question #2 - Page 30, Incentive and disincentives for non-profits. This is confusing. Can you give us an example of such? Would placing funds in a research fund for seeding or supplementing existing projects, administrated by the Contractor, be an example?

Answer #2 - Although this is a good idea, it would not be appropriate because it would involve an independent research and development project, which is unallowable under the contract mechanism. The incentive you described is best suited for grants. A good example that comes to mind is, a piece of equipment you may be wanting/needing for your lab. Or, you may want to attend a specific scientific meeting, but due to lack of funds, you're unable to do so.

Question #3 – What is going to happen to the samples after the contract is finished? It is stated the US Government owns the samples for five years. What happens to the samples then? Are they transported to US Government facilities, or is the Contractor expected to provide storage for five years after the contract?

Answer #3 – The Contractor would not be expected to provide storage after the contract is ended. The Contractor is expected to outline the plan for completion of transition as outlined in the RFP. This plan should include sample transfer if necessary to government, or facilities of another Contractor, or, disposal of the samples, as directed at that time by the NINDS Project Officer.

Question #4 – On Page 30 (g), the Estimate of Effort refers to 74,880 labor hours for the entire contract period. On how many samples is this based?

Answer #4 – The sample estimates are outlined on page 59 of the solicitation, as a total of 2000 samples per year, to be added to the repository, and 500 withdrawn per year. Actual numbers will vary. These numbers are given for estimation purposes.

Question #5 – Can you provide a more concrete explanation of "utilize clinical diagnostic criteria as designated by the Project Officer", which appears on page 42, (5)?

Answer #5 – The clinical diagnostic criteria is meant to indicate the clinical data elements (CDEs). This is defined in the glossary (page 73) as "subject data requirements for every dataset, regardless of provider, which will include all of the essential elements that will be needed by users." The Project Officer will work with the NINDS Repository Internal Steering Committee to generate documents which will include information such as age, age of disease onset, diagnosis, and diagnostic information which will assure standardization of sample collection for a given disease set of samples. These CDEs will be provided to the Contractor at the state of the Contract.

Question #6 – Regarding the ownership of Government Furnished Property, can the assumption be made that it will be provided at GSA prices? Does this refer to all equipment or just electric freezers and liquid nitrogen tanks storing DNA or cryopreserved cells, respectively?

Answer #6 – No, the assumption can't be made that Government Furnished Property will be provided at GSA prices. Funding for equipment, if provided, will be based upon the lowest price, which should be obtained by requesting competitive quotes from three (3) different vendors.

Question #7 – On what level of activity should the bid be submitted? A range of 6,000 to 14,750 cell lines over the full period of the project has been indicated. Given the economies of scale as the size of the project increases, what is the appropriate level?

Answer #7 – The costs must offset the fees for withdrawal.

Question #8 – It is understood that the Government intends to award a performance based, cost plus award fee contract to those organizations which can earn a fee. Please confirm that offerors can propose a total potential fee that includes a base fee amount plus an award fee that will be determined in accordance with evaluation procedures established in the contract.

Answer #8 – Yes, offerors can propose a total potential fee that includes a base fee amount plus an award fee that will be determined in accordance with evaluation procedures established in the contract.

PROPOSAL CHECKLIST RFP-NIH-NINDS-02-03 HUMAN GENETIC RESOURCE CENTER: DNA AND CELL LINE REPOSITORY

THE FOLLOWING DOCUMENTS MUST BE SUBMITTED WITH YOUR TECHNICAL AND BUSINESS PROPOSAL

(Do not submit checklist with your proposal)

| | For Educational Institutions or Non-Profit Organizations (not eligible to receive a fee) have you prepared the required Non-monetary Incentives/Disincentives? See Page 30 of the solicitation for additional information. Reminder, monetary values MUST be itemized and included under "Other Direct Costs" in your business proposal. |
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| | Include the Tax Identification Number (TIN) and Dun & Bradstreet Number. See page 2 of the solicitation cover letter for additional information. |
| | Section K of the solicitation, requires you to submit the Representations and Certifications, and Other Statements of Offerors, with your proposal. See page 24 for the website address. |
| | Past Performance Information is required as part of your <u>BUSINESS</u> proposal. See page 40 of the solicitation for further information. You must also provide comparable information on all subcontractors that your organization proposes to perform a major subcontract under this effort. A major subcontract is defined as a subcontract that exceeds \$500,000. |
| Ц | Provide a copy of your organization's current indirect cost rate agreement. See page 47 of the solicitation. |
| | If your organization is proposing to use a subcontractor, you must include a commitment letter from the subcontractor's organization. See page 51 of the solicitation, paragraph 7, for further information. |
| | Section M, EVALUATION FACTORS FOR AWARD, page 54 of the solicitation requires the following documents to be submitted along with your proposal: Paragraph C: requires submission of a Data Sharing Plan and Intellectual Property Plan Paragraph E: requires submission of the Small Disadvantaged Business Participation Factor. Refer to Attachment 10, located on page 92. This form must be completed and submitted along with your BUSINESS proposal. |
| | The following attachments must be completed and submitted with your proposal: Attachment #4, entitled, SUMMARY OF LABOR AND DIRECT COSTS, see page 77. Attachment #5, entitled, PROPOSAL SUMMARY AND DATA RECORD, see page 78 Attachment #6, entitled, SUMMARY OF ANNUAL COSTS, see page 80 Attachment #7, entitled, SUMMARY OF RELATED ACTIVITIES, see page 81 Attachment #8, entitled, DISCLOSURE OF LOBBYING ACTIVITIES, see page 82 Attachment #10, entitled, SMALL DISADVANTAGED BUSINESS PARTICIPATION PLAN OUTLINE, see page 92 |
| | <u>PLEASE NOTE</u> : YOU MUST INDICATE YOUR ACKNOWLEDGEMENT OF THE AMENDMENT TO THE SOLICITATION BY EITHER ONE OF THE FOLLOWING METHODS: BY USING THE PROPOSAL SUMMARY AND DATA RECORD, ATTACHMENT #5, <u>OR</u> BY ACKNOWLEDGING RECEIPT ON EACH COPY OF THE OFFER SUBMITTED. |
| | Commitment letters for use of consultants and other personnel to be hired must be provided. See page 43 of the solicitation, paragraph c.3. for further information. |
| | AN ADDITIONAL COPY OF THE BUDGET MUST BE PROVIDED ON A 3.5" DISKETTE IN MICROSOFT FXCEL® FORMAT. |