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

AMENDMENT OF SOLICITATION NO.: RFP-NIH-NINDS-02-03

AMENDMENT NO.: 02

EFFECTIVE DATE: April 30, 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 additional responses to technical questions submitted by potential offerors.

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

Question #1 – It is understood that any resulting contract award will be made on or about September 30, 2002. When does the Government expect that the Contractor will be required to receive samples?

Answer #1 – The Contractor should be prepared to receive samples at the beginning of the contract period.

Question #2 – In regard to the Statement of Work, the following questions have been asked:

a. **Page 65, 4.4: Storage –**

1. **Question - Are there guidelines already established for the minimum/maximum number of cell lines and DNA samples that are to be stored?**

   Answer – There are no established guidelines at this time. This is intentional, to allow flexibility in Repository function and design. It is very difficult to accurately estimate the number of samples being stored, as the number of samples the repository can process depends on the costs of the number stored, offset set by the number requested resulting in collected fees. Furthermore, the number of samples received depends on the number of submitted samples and the timing of sample arrival. Samples will not arrive in a steady, standard fashion; they will arrive in larger or smaller quantities each month. However, the estimates are that there will be between 50 and 200 samples arriving per month. Sample receipt is expected to be less in the first year of the contract, as it is expected it will take time for sample collection and submission to occur.

2. **Question - The Contractor shall store cell lines and DNA in a manner that the viable cell lines which are produced through cell expansion as set forth in Section 4.3.2, are available to requesting researchers during the contract period of performance and that will allow viable cell lines to be transferred to another repository at the end of the contract period of performance. Time line? Months/years? Priority order established for researchers?**

   Answer – As stated in the Statement of Work,

   "The Contractor shall develop plan for transition, resource protection and retention, and data transfer and collation for execution in the event the contract is terminated or expires.

   The Contractor shall provide a summary to the Project Officer three months prior to the end of the contract. The summary must include a full inventory of cell lines, DNA, and plasma; a report of costs incurred and fees collected for each year of the contract; and a list of submitting and withdrawing investigators in hard-copy and electronic formats.

   Twelve months prior to the expiration of the contract period of performance, the Contractor shall propose a system for the transfer of all cell lines, other biological material, electronic databases, data management systems, and files to a storage facility or successor Contractor. Upon approval of the Contracting Officer, the Contractor shall transfer all electronic databases, data management systems, and files as directed by the Contracting Officer."

Therefore, it is the Contractor's responsibility to develop the transition plan should the contract be terminated or transferred to another Contractor. Which of these will be done, cannot be predicted until the expiration date of the contract approaches. The time line will be ultimately proposed by the Contractor, reviewed and approved, or revised and approved by the Contracting Officer, within the timeline as noted above. The timeline for the completion of the particular plan will be developed by the Contractor and submitted.

3. **Question - The Contractor shall store cryo-preserved aliquots of each sample in a remote location, different physically than the Repository, to provide for disaster recovery, in case the Reposiotry or its contents are damaged or destroyed. By ". . . remote location, different physically than the Repository . . .", does this imply that storage units must be located in a separate building or can storage be facilitated in another location of the same building?**

   Answer – The intention of this requirement is to physically protect the unique resources of the repository from natural disasters (including floods, fire, tornadoes), acts of terrorism or sabotage, power outages, and other circumstances which could seriously damage or even eliminate the repository including its data and sample collection. Therefore, in general terms, it can be stated that the safest setting would be in a physically remote location, with separate power supply and otherwise, free standing for backup of samples and data to occur. If the Contractor can propose a situation where the back up storage facility would not be subject to the same destruction as the rest of the building where the resource is stored, even when within the same building, then, this may be reasonable as a general statement (albeit somewhat hard to conceive of in this context).

b. **Question - Page 66, 4.5.2: Distribution to Other Qualified Investigators - Are IRB's of Contractor institution not withstanding?**

   Answer – The intent of the IRB language is to insure that any sample received, stored, and/or distributed by the Repository is collected under an IRB approved project, and that samples were collected from subjects using informed consent.

c. **Question - Page 69, General Reporting Requirements: Sample characteristic summary, regarding confidentiality, it appears the data tabulation required is in direct conflict with what will be given or not given to the Contractor. Please explain.**

   Answer – The following information, directly taken from the Statement of Work, should help clarify this confusion:

   > "The Contractor shall also provide data collection instruments such that all data accompanying a sample possess a unique, confidential and standard subject identifier; and that allow clinical diagnosis and pedigree structure to be analyzed without revealing subject identities.

The Contractor shall ensure that the data accompanying each sample is adequate for research purposes. As a minimum, the data must document the following sample characteristics:

- Subject Identifier
- Kindred Identifier
- Relationship to other samples in the Repository or other public repositories
- Gender
- Death status
- Ethnicity
- Age of subject at collection
- Best estimate of age of subject at disease onset
- Twin status
- Diagnosis (or control, or unaffected status)
- Clinical Data Elements (CDEs)"

Based on this, the Contractor shall receive no individually identifying information (name, social security number, etc) but will receive information regarding family history, linked through the pedigree number as assigned by the Contractor. In other words, the information is not anonymous, but is masked; the Contractor is not to directly contact the subjects.