ARTICLE C.1. STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below:

BACKGROUND INFORMATION

Storing and allowing subsequent use of biological materials and associated data collected in clinical studies is one way for the NIDDK to meet its responsibility to maximize the value of these studies. A collection of the biosamples and associated clinical, diagnostic, genotypic, pedigree structure and/or other data will become a resource that advances the development of diagnostic and treatment tools for many diseases. The NIDDK Biosample and Genetics Repositories, which will be established through this Request for Proposals and which are described in other Statements of Work, will house biological materials collected in large clinical studies. The project described in this Statement of Work, which will be referred to herein as "The Data Repository," will eventually store the data from these large studies, including data associated with the stored biosamples. To date, no central repository of data from many different studies has been available to the investigators interested in studying the many diseases that are the focus of NIDDK research.

The Data Repository will store, maintain, perform quality control assessments, and distribute data important to the study of diseases under the mandate of the NIDDK. In addition, the Data Repository will consult with new and ongoing studies to assist them in developing databases that will eventually be reposited and made available to other researchers. The Repository, by fostering the development of highly usable public data sets, will allow re-analysis of these data and, where relevant, of specific biosamples, thus encouraging work by junior investigators, investigators with novel approaches, and others not included in current collaborations. It will decrease redundant sample and data collection efforts, and optimize use of study data and samples.

Towards the above ends, the objective of this contract will be to establish the NIDDK Data Repository, in order to accomplish the following in a highly efficient, rapid, and cost-effective manner:

- Assist new and ongoing studies in developing databases that will eventually be made available to other researchers
- Assist study coordinating centers and the NIDDK Biosample and Genetics Repository in setting up systems to cross-reference samples and associated data
- Receive and test the utility of electronic databases from completed studies
- Maintain and distribute those databases
- Provide timely and correct analyses of databases in response to researcher inquiries
- Create and maintain a website for all of the NIDDK Central Repositories

The information systems, consulting, and database archiving tasks outlined in this statement of work are highly technical, and require extensive experience, expertise, and long-term commitment. The data from each study represent the efforts of hundreds of investigators over five or more years to improve the public health through biomedical research, and the voluntary participation of hundreds or thousands of patients and family members. The data cannot be replaced without great expense and effort, and, therefore, it is essential that they be protected from loss, damage or misuse. The Contractor's project director must have extensive experience in successful database management. The Contractor's staff must be highly trained to work with, maintain, and analyze numerous databases, including those in Oracle and other DBMS's. As all the work is with data from human subjects, all staff must be familiar with human subjects protections and be sensitive to the bioethical issues involved in handling subject data. Finally, the Contractor must have a demonstrable long-term interest in providing these services, to ensure that there is continuity throughout the period of the contract.

To the best of our knowledge, there are no grants, cooperative agreements, or contracts currently funded by NIDDK, or by other government agencies, which can perform all of the required work, create all of the required deliverables, and widely distribute clinical data to the scientific community.

A. Statement of Work

Task 1. Receive and test the accuracy, completeness and validity of electronic databases of participant information from completed studies that include clinical, diagnostic, genotypic, pedigree structure and other data, along with supporting documentation.

a. The Contractor shall work with Data Coordinating Centers and other investigators from NIDDK-funded studies on an ongoing basis during the course of the study to prepare for receiving and testing the accuracy, completeness and validity of electronic databases. Database formats may differ from study to study. Individual studies may contain multiple files linked by encrypted patient identifiers. The Contractor shall work with Data Coordinating Centers of NIDDK-funded projects to ensure that these phenotypic databases are in a format that allows rapid and efficient searching and production of files for distribution.

b. In addition, the Contractor shall ensure that the database is accompanied by supporting documentation that describes the study protocols and summarizes the data collected.

c. The Contractor shall post the Manual of Operations from each study providing a database on a Website, and/or make it readily accessible.

d. The studies that are now completed whose datasets will be acquired by the Repository include, but are not limited to: Modification of Diet in Renal Disease (MDRD), and the first phase of the Interstitital Cystitis (IC) study.

Task 2.Consult with data coordinating centers from new and ongoing studies to help develop databases that will eventually be made available to other researchers

The Contractor will work with numerous other studies to prepare for eventual repositing of data sets, including, but not limited to: Medical Therapy of Prostatic Symptoms (MTOPS), Chronic Renal Insufficiency Cohort Study (CRIC), Boston Area Community Health (BACH) Study, Hemodialysis (HEMO) Study, Prevention And Treatment Of Type 2 Diabetes In Children And Adolescents, Folic Acid for Vascular Outcome Reduction in Transplantation (FAVORIT) Trial, and the Epidemiology of Diabetes Interventions and Complications/Diabetes Control and Complications Trial (EDIC/DCCT) Family Study.

Task 3. Work in a cooperative fashion with the Project Officer, the External Advisory Committee, and the Steering Committee.

The Contractor shall cooperate with the Project Officer, the External Advisory Committee, and with Contractors and their representatives from the NIDDK Biosample and Genetics Repositories, through participation in the Steering Committee and through other activities. This includes, but is not limited to, cooperation in developing a sample labeling system, methods for cross-referencing, and database integration. In addition, the Contractor shall facilitate site visits by the Project Officer, the Steering Committee, and other groups, as directed in writing by the Project Officer.

Task 4. Maintain the confidentiality of subjects by removing all traditional personal identifiers from data

a. Datasets will be received without personal identifiers and thus are unlinked to the subjects; such materials are "anonymous" subjects. The Contractor shall not accept any information, nor use any information collected under this contract, that would permit the Contractor as the keeper of a record system to establish the identity of a given subject or query the databases and retrieve information for an individual subject whose identity is known from some other source.

b. Traditional personal identifiers that may be utilized to establish the identity of individual subjects (e.g., surname, address, social security number, etc.) shall not be provided nor accepted by the Contractor. Instead, the Contractor shall work with the study's Data Coordinating Center, and the NIDDK Biosample and Genetics Repositories to develop an identifier code for each subject that will link the clinical and descriptive data to stored biosamples. Thus, all data received by the Contractor shall be untraceable to their original sources.

c. The Contractor shall not use the data for any purpose other than that specified in this contract, without prior written approval of the PO.

d. The Contractor shall assure that all investigators have adequate approval from an Institutional Review Board (IRB), for the collection and use of data submitted to the repository. The Contractor shall apply to the Office for Human Research Protections (OHRP) at the Department of Health and Human Services for a project assurance number, if such a number has not been assigned to the Contractor. Obtaining a project assurance number represents a binding commitment to minimum standards for the protection of human subjects, which safeguards the rights and welfare of all human research subjects. In addition, the Contractor shall meet the requirements of The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other relevant government regulations governing health information from human subjects.
e. The Contractor shall obtain blank copies of all the informed consent forms used in the collection of the data received by the Contractor.

Task 5. Provide timely and accurate analyses of databases regarding the availability of samples, including the determination of the feasibility of the repository to meet the needs of a research request, such as the number of samples available that meet specific criteria.

a. The Contractor shall be able to query the various databases to respond to inquiries from researchers and from the NIDDK about the data, and/or about the biosamples that are stored by the NIDDK Genetics and Biosample Repositories. Given that this is a highly detailed and complex task, the Contractor shall ensure that the contract is staffed at all times by personnel who are qualified to maintain and search databases.

b. When investigators request that the Contractor query the database or databases in the repository, the Contractor shall respond to that request in a timely manner. Responses to queries should be provided within a maximum of 2 weeks after the request is received. The Contractor shall develop a standard Letter of Agreement that will be signed by researchers making requests.

c. The Contractor shall charge fees for carrying out detailed queries of stored databases for inquiries that require more than 2 hours of effort. Within 2 months of the award of the contract, the Contractor shall establish an appropriate system for the accounting and reporting of fees in accordance with the fee schedule established jointly with NIDDK. The Project Officer retains the right to waive the access charge for a recipient. The Contractor shall establish a process, with approval of the Contracting Officer, to ensure that all such fees are promptly collected and accounted for accurately, and offset against contract costs in a proper and timely manner. The Contractor shall not distribute materials before payment in full is received, unless the Project Officer has waived the fees. Payment shall be in the most expeditious format (e.g., check, purchase order, electronic transfer) possible. Income received from fees charged shall be utilized to offset contract costs. Such income shall be reflected on the Contractor's invoice for the month it is received.

Task 6. Maintain and distribute stored databases or selected portions of stored databases to qualified investigators granted access by the Project Officer

a. The Contractor shall maintain the finished databases and distribute them, or selected portions of them, to qualified researchers, as directed in writing by the Project Officer. The quality of the stored databases and of the responses to researcher inquiries shall be assessed periodically.

b. As directed in writing by the Project Officer, the Contractor will prepare edited versions of databases for public distribution, which contain selected descriptive information about subjects in the study and the types of samples available.

c. The Contractor shall not use the data for any purpose other than that specified in this contract, without written approval of the PO.

d. When investigators granted access by the Project Officer request data, the Contractor shall transmit the requested data within 2 weeks of the request.

Task 7. Establish and maintain an information system to track all inquiries about data and requests for databases

The Contractor shall maintain a database that records all inquiries about the stored data and databases, and that lists all requests for copies of databases or portions of databases. The database shall include the date of the request or inquiry, the name, phone number and affiliation of the inquirer, and the date and nature of response by the Contractor.

Task 8. Establish and maintain general Quality Control (QC) and Quality Assurance (QA) programs.

The Contractor develop and implement general QA/QC programs covering activities critical for the successful operation of the repository. These are general operating procedures that are not specific to particular databases. The QA/QC programs shall include, but not be limited to:

(a) Protocols for assessing the integrity of the databases
(b) Plans for tracking the quality and speed of responses to inquiries and requests
(c) Protocols for assessing the usability of the databases and supporting materials that are distributed

The Contractor shall submit, within 8 calendar weeks of award, a detailed protocol for these general QA/QC procedures that will be implemented for any and all databases acquired by the repository. Revisions specified by the Project Officer will be completed within 2 weeks, and the final version will then be submitted for approval by the Project Officer.

Task 9. Provide security and back-up systems and a plan for disaster recovery.

a. The Contractor shall establish systems to prevent loss of data and databases in case of physical damage or equipment failure. This includes a daily backup of all changes to electronic databases to protect against the accidental data loss. In addition, a backup copy of each database shall be stored in remote, secure location in a waterproof and fireproof container. This remote backup copy shall be updated weekly if there are any changes to the database. In addition, the Contractor shall establish systems that prevent electronic or physical access to data or computers storing data by unauthorized individuals.

b. The Contractor shall provide, within 8 calendar weeks of award, a detailed protocol describing security and back-up systems. Revisions specified by the Project Officer will be completed within 2 weeks, and the final version will then be submitted for approval by the Project Officer. The protocol shall be updated annually.

Task 10. Maintain a public forum, including a web site, as a resource for users of the repository, and as a tool for public education about the repository and its goals, including a list of publications resulting from use of repository samples.

a. In coordination with the NIDDK Biosample and Genetics Repositories, the Contractor shall create, maintain, and regularly update a public Web site, with appropriate links to other NIDDK, government, professional organization, and foundation sites. The site will include data regarding the resources, policies, and other information of each NIDDK repository. The Web site shall include tables of descriptive information describing the current status of each repository, including a brief description of each study, data dictionaries, and the number of subjects and types of samples and data available, distribution agreement forms, instructions and applications for obtaining databases, and policies governing the repository. The Web site should be established within 3 months of contract award.

b. The Contractor shall solicit a list of publications from researchers who received data from the repository which have resulted from the use of the data and document these on the website. In addition, the Contractor shall solicit and post similar lists from the NIDDK Biosample and Genetic Repositories. The Contractor shall also search relevant scientific literature databases, including those maintained by the National Library of Medicine, to identify publications that used data supplied by the NIDDK Data Repository. Electronic literature searches shall be carried out at least every 3 months.