PUBLIC INFORMATION AND COMMUNICATION SERVICES (PICS)
NIH -TASK ORDER

**RFTOP# 151**

**TITLE: Administrative Coordinating Center for the NHLBI DNA Re-sequencing and Genotyping Program HV-04-12**

PART I–REQUEST FOR TASK ORDER PROPOSALS

A. Point of Contact Name: Gwennifer Epps
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**Proposal Address:**
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Division of Extramural Affairs, COB
6701 Rockledge Dr, MSC 7902 (Rm 6016)
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**If using courier service: Zip Code 20817**

**Billing Address:**
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National Heart, Lung, and Blood Institute
Division of Extramural Affairs, COB
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Bethesda, MD 20892-7902

B. PROPOSED PERIOD OF PERFORMANCE: June 1, 2004 through May 31, 2009. The target award date is May 17,2004.

C. PRICING METHOD: Performance-based Cost Reimbursement. The Government anticipates awarding one task order as a result of this RFTOP.

D. PROPOSAL INSTRUCTIONS: Proposals must be submitted to the contracting officer: Betty Nordan. Written proposals shall be prepared in electronic formats such as Word Perfect, MSWord, Excel, or hard copy. Please enter the following text in the subject line, "RFTOP# 151 Proposal." A signed task order form (last page of the RFTOP) will be requested later. Offerors shall limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Specifically, the Technical Plan (objectives, approach, methods and procedures, and schedule) of the Technical Proposal shall not exceed 50 single-sided pages or 25 double-sided pages. This page limitation does not apply to the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, other support, cost information, and literature cited. Appendices shall be limited to 100 single-sided pages or 50 double-sided pages. Pages in excess of this will be deleted and will be neither read nor evaluated. Each page of the Technical Proposal must be numbered sequentially. No page limit has been placed on the Business Proposal, however, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

The number of copies required for each part of your proposal are:

TECHNICAL PROPOSAL: ELECTRONIC AND * ONE (1) PAPER ORIGINAL * AND TEN (10) PAPER COPIES.

BUSINESS PROPOSAL: ELECTRONIC AND ONE (1) PAPER ORIGINAL * AND FOUR (4) PAPER COPIES.

E. RESPONSE DUE DATE: Thursday, October 23, 2003 at 4:00PM local time. Upon delivery to 6701 Rockledge Drive, all proposals must be screened by X-ray before delivery to room 6016. **ALLOW EXTRA TIME for this process!**

F. TASK DESCRIPTION: See attached Statement of Work.

G. EVALUATION FACTORS: See Below.

**TITLE OF TASK ORDER: Administrative Coordinating Center for the NHLBI DNA Re-sequencing and Genotyping Program**

**STATEMENT OF WORK - ADMINISTRATIVE COORDINATING CENTER**

**NOTE TO OFFERORS:** This RFTOP procurement will result in the award of a performance-based task order. As such, offerors shall propose measurable performance standards to enable assessment of contractor work performance.

## A. General Description of the Required Objectives and Desired Results

The overall objective of the National Heart, Lung, and Blood Institute (NHLBI) DNA Resequencing and Genotyping (RS & G) Program is to obtain reliable, rapid, and cost-efficient DNA resequencing and genotyping of candidate genomic regions potentially important in the disease pathways of heart, lung, blood, and sleep disorders. This resequencing and genotyping information will assist ongoing investigations of the genetic components involved in the cause, variable outcome, and progression of heart, lung, blood, and sleep diseases and disorders. The RS & G Program will consist of two to five Laboratory Centers capable of performing high-throughput, large-scale DNA resequencing and/or genotyping to discover and type DNA variations for heart, lung, blood, and sleep investigators and one Administrative Coordinating Center (Coordinating Center) to provide the logistical support for the entire RS & G Program.

At award of the contracts, each Resequencing Center will produce at least 60 Mb of sequence per year with an error rate of no more than 1/10,000 bases (no less than 99.99% accurate) and each Genotyping Center will generate at least 500,000 genotypes per year with an error rate of no more than 1%. The RS & G Program's initial DNA resequencing effort (sum of all DNA Resequencing Centers) is expected to be capable of sequencing at least 100 genes per year of an average size of 25 Kb in 48 chromosomes. The RS & G Program's initial genotyping effort (sum of all Genotyping Centers) is expected to be capable of customized genotyping of at least 10 genes per year with approximately 10 single nucleotide polymorphisms (SNPs) per gene in an average of 2,000 individuals. By the end of the third year, each Laboratory Center will be expected to have doubled its production. The Laboratory Centers will receive DNA samples from investigators approved to utilize the resequencing or genotyping service and will not be receiving any tissues or cells. A Laboratory Center offeror may propose to perform up to 100% of the RS & G Program's capacity for resequencing and/or genotyping.

The Principal Investigator of the Administrative Coordinating Center is expected to work closely with Principal Investigators from the Laboratory Centers and with NHLBI. The Administrative Coordinating Center contract will be awarded 3 months prior to contracts for the Laboratory Centers to provide adequate time to develop the RS & G Program infrastructure and to organize the first Steering Committee

meeting. The Administrative Coordinating Center responsibilities will be to establish and maintain a web site, advertise and market the RS & G Program to the research communities; process the requests for use of the Laboratory Centers, make effective work assignments for the Laboratory Centers, provide logistical support for the three RS & G Program committees, and facilitate communication with NHLBI.

The work of the Laboratory Centers will be in four phases. During Phase I, the Protocol Development Period (Lab Center months 1-6), each Laboratory Center will prepare a draft of its Laboratory Manual of Operations, and work with the Administrative Coordinating Center and NHLBI staff to establish the overall policies, guidelines, and procedures for the RS & G Program. In Phase II, the Pilot Testing Period (Lab Center months 7-12), the Laboratory Centers will test and modify the newly established policies, guidelines, and procedures while resequencing or genotyping at their initial levels. During Phase III, the Regular Production Period (Lab Center months 13-36), the Laboratory Centers will start with resequencing or genotyping samples at their initial production level while improving their production, so that by the end of month 36 they will have doubled their production without an increase in cost. In Phase IV, the High Production Period (Lab Center months 37-60), the Laboratory Centers will perform at a level that is at least double their initial capacity and production.

The RS & G Program, through the Administrative Coordinating Center, will solicit requests from investigators wanting to have their chromosomal regions of interest resequenced and/or genotyped. An Evaluation Panel consisting of expert scientists from outside the RS & G Program and the NHLBI will review the requests for access. NHLBI approved requests will be distributed to the Laboratory Centers by the Administrative Coordinating Center as appropriate for optimum workflow. Requests from users will be solicited to match the developing capacity of the Laboratory Centers. During Phase II, investigators applying to use the service are expected to have identified potential candidate genes related to the disease or trait of interest, in a single candidate genomic region, for resequencing and/or genotyping (5-10 genes expected per request). During Phase III requests may be submitted for other candidate genes and named genes if the previous search of candidate genes was not informative. For example, investigators could submit requests for resequencing or genotyping of all relevant named genes (20-50 expected per request) in the region of interest. In Phase IV, when full capacity is established, investigators may request examination of all putative genes in the candidate region (40-70 expected per request). This effort will be started on a limited scale until the cost of these efforts has decreased due to increased efficiency or new technology.

Under the performance based contracting approach, the Administrative Coordinating Center and the Laboratory Centers annually will propose specific goals and timetables for their Performance Assessment Scheme (PAS) for the upcoming year.

The PAS is also called a Quality Assurance Surveillance Plan. The Coordinating Center and Laboratory Centers will be reviewed annually by the Oversight Committee to determine whether they have met the PAS requirements. The recommendations from the Oversight Committee will be forwarded to the NHLBI for approval.

**Note to Offerors***:* The technical proposal should include suggested changes or additions to the draft PAS for Phases I and II. See a draft PAS in this RFTOP.

The major output from the RS & G Program is sequencing and genotyping data and results for investigator use and, on an appropriate timeframe, to have sequencing and variation results and data placed in publicly accessible databases. The major outputs of the Coordinating Center are a web site, successful marketing to investigators, a manual of operations, meetings, reports, Laboratory Center workload assignments, and information transmitted to public data bases. The major outcome of the Coordinating Center contract is the facilitation of the processes and procedures for the RS & G Program. The successful outcome of the RS & G Program will be the identification of genetic variation associated with the cause, variable outcome, and progression of heart, lung, blood, and sleep disorders and diseases.

## B. Background Information

The NHLBI is committed to determining the genetic contribution in the cause and/or progression of heart, lung, blood and sleep diseases and disorders. To help investigators identify large regions of the human genome that appear likely to be involved, the Institute established the NHLBI Mammalian Genotyping Service in 1994. This effort has provided the opportunity for whole genome scans using microsatellite markers spaced approximately 10 cM apart. Its establishment was made possible by technical advancements and the development of high-throughput systems. Linkage analyses using the available microsatellite markers together with completion of the Human Genome Project has greatly enhanced the speed with which candidate genes can be found. Presently, there is an increased need for resequencing and genotyping so that investigators can identify the specific genes and variations that influence the development and/or progression of these disorders. Therefore, the NHLBI is establishing the RS & G Program to provide large-scale, high-throughput DNA resequencing and genotyping services that are reliable, rapid, and cost-efficient.

The most abundant form of polymorphism or genetic variation in the human genome is SNPs. These are found at about 1 per 1000 base pairs. Currently, approximately 4 million SNPs have been identified in coding and non-coding regions. The single nucleotide substitutions can result in dramatic changes or subtle modifications. SNPs in coding regions can change the amino acid sequence of a protein leading to

altered catalytic function or produce stop codons resulting in truncated proteins. SNPs also can result in sequences that prevent normal protein folding, necessary post-translational modifications, or normal interactions between proteins. SNPs in non-coding sequences can alter proper RNA processing leading to splice site variants or change in the ability of regulatory regions to function normally resulting in altered protein expression. For rare Mendelian traits, SNPs are the most frequent form of disease-causing mutation. For complex diseases, SNPs can provide subtle changes that occur frequently leading to the numerous biological consequences that are associated with increased susceptibility to disease.

The NHLBI will establish Resequencing Centers to resequence samples from known populations to discover DNA sequence variation potentially contributing to heart, lung, blood, or sleep disorders. Many laboratories are now doing sequencing in a high-throughput, high capacity, cost-effective mode making resequencing feasible for variation discovery. This approach has gained in use because of its automation, accuracy, speed, and sensitivity. In the RS & G Program, the variation discovery will be performed using known human variation panels of DNA such as those available from the Coriell Cell Repository, Coriell Institute for Medical Research Repository. For example, the DNA Polymorphism Discovery Resource has been designed to reflect the diversity in the human population (http://locus.umdnj.edu/nigms/products/pdr.html). The results of this effort will provide the relative frequency of a SNP and its allele frequency. An understanding of the organization of the variable sites within a gene or a specific region of the genome is also important. Given the high frequency of variant sites within a particular gene, the identification of areas of correlated SNPs, known as haplotype blocks, will be important to allow the important gene variants to be typed with a limited number of SNPs. Several different algorithms have been developed for haplotype analysis. Approaches which optimize the selection of informative sites to be genotyped in large-scale association studies will be key to helping NHLBI investigators test specific hypotheses and will streamline the costs of these analyses.

The NHLBI will establish Genotyping Centers that can provide accurate, high-throughput, high capacity genotyping to heart, lung, blood and sleep investigators in a timely manner. It is anticipated that genotyping will be performed in well-characterized population samples of approximately 1000-4000 individuals provided by the investigators approved to use the RS & G Program. The main focus of the program will be the genotyping of SNPs as these are relative stable, reproducible, and likely to provide much of the needed information. Several platforms have been developed to perform SNP genotyping. Genotyping for polymorphisms other than SNPs will be necessary and high-throughput methods for these are also sought.

Through the establishment of the Laboratory Centers, NHLBI investigators will have the ability to resequence all candidate genes (coding and non-coding regions),

named genes, or putative genes in a region; and then genotype specific variations in a large number of affected and unaffected individuals. The Laboratory Centers will provide services for investigators approved to use the RS & G Program at no cost to the investigator. The NHLBI anticipates awarding one to two DNA Resequencing Centers and one to three Genotyping Centers. The number of Laboratory Centers awarded will be based on the capacity of offerors and the need for services. Award of the Laboratory Centers is anticipated through a separate solicitation (NHLBI-RFP-HV-04-13). The RFP for the Laboratory Centers can be found at the NHLBI website, http://www.nhlbi.nih.gov/funding/inits/index.htm#rfp, and at the Federal Business Opportunities website, FedBizOpps, http://www.fedbizopps.gov/.

The NHLBI supports two programs that have provided the foundation for the RS & G Program. The Mammalian Genotyping Service (with Marshfield Medical Research & Education Institute under NHLBI's contract N01-HV-48141) provides whole genome scans. To use this service, investigators submit requests through the Mammalian Genotyping Service website http://research.marshfieldclinic.org/genetics/Genotyping_Service/mgsver2.htm). These requests are prioritized by a group of experts from outside of the Mammalian Genotyping Service and the NHLBI similar to that proposed for the RS & G Program. The NHLBI also supports a large program for the generation of various resources to help stimulate progress in genomics. The NHLBI sponsored Programs for Genomic Applications (PGAs) have a limited amount of DNA resequencing and genotyping. Information about these efforts can be found at http://www.nhlbi.nih.gov/resources/pga/index.htm. Links to the eleven individual web sites are available from this web page.

## C. Detailed Description of the Technical Requirements/ Tasking Section

The **ADMINISTRATIVE COORDINATING CENTER** shall:

**During Phase 1 - Protocol Development (Coord Center months 1 - 9)**

1. Contribute to and facilitate all aspects of the Steering Committee to develop and implement the procedures and processes for the RS & G Program. Forward Steering Committee recommendations on procedures and processes for NHLBI approval. Develop a Manual of Operations for the Program and related standardized tracking, formats, and reports for management information and for all non-laboratory aspects of RS & G Program operations.

2. Coordinate, arrange, provide necessary information and materials, and otherwise facilitate meetings and conference calls of the Steering Committee, Evaluation Panel, Oversight Committee, and any other groups determined necessary for the RS & G Program. Prepare and distribute minutes or

reports according to the needs and time constraints of each group.

**Note to Offerors**: See Consortium Committees for additional information on the Steering Committee, Evaluation Panel, and Oversight Committee.

3. Develop and implement effective and efficient communication interfaces for information to and requests from the research community for:

a. Outreach/Promotion: The Administrative Coordinating Center shall inform the research community of the availability of the Laboratory Centers and services. Outreach/promotion shall be sufficient to result in adequate requests from high quality studies to fully utilize the RS & G Program's capacity. Advertisements in journals, exhibits at national meetings, and a web site shall be used.

The web site shall be established and opened to public access. The web site shall be operational no later than five months after task order award. Accepted industry tools and applications shall be used to develop the web site. The site shall be hosted in a manner that allows NIH staff access to the files for minor edits and updates. Technical details of the site design and operation shall be well documented. Rigid design structure and customized graphic elements shall be avoided; the site shall be designed to easily accommodate change. The site must comply with all applicable Federal regulations, including Section 508 of the Rehabilitation Act of 1973 (29 USC 794d). See http://www.section 508.gov and http://www.nih.gov/od/ocpl/wag/resources/pubs/develop.html. The site URL shall end in "nih.gov" not ".com". All source material for the site shall be returned to NHLBI. The web site and all related software developed specifically for this contract shall be owned by the Government.

Information from this web site shall not be used for any purpose other than those of the RS&G Program. Names, e-mail addresses, phone numbers etc. shall be not be used or made available to anyone for any purpose not exclusively authorized by NHLBI under the RS&G Program.

All brochures, advertisements, marketing strategies, the exhibit booth design, and web site plans must be approved in advance by the NHLBI Project Officer.

The contractor shall provide storage for the exhibit booth when not in use.

b. Applications/Processing: The Administrative Coordinating Center shall develop procedures and formats for the following:

1) Information and submission procedures for potential applicants;

2) Receipt of requests from applicants. The Administrative Coordinating Center shall develop procedures to receive, log, and track the requests to use the services. Electronic submission will be mandatory. Note: The Coordinating Center shall confirm prior approval by the applicant's Institutional Review Board before submitting the application to the Evaluation Panel.

Following the prioritizing process and approval by NHLBI,

3) Priority or disapproval notices to applicants;

4) Procedural information for submission of samples by successful applicants;

**Note to Offerors**: The Laboratory Centers shall transmit the sequencing and genotyping data directly to applicants. On a schedule to be implemented in accordance with NIH sharing policies, the Laboratory Centers shall release sequencing and variation results or data to the Data Base of Single Nucleotide Polymorphisms (dbSNP), to GenBank, and to other public databases.

4. Develop and implement effective and efficient communication and operational interfaces with Laboratory Centers, maximizing the use of electronic communications. The Coordinating Center shall:

a. Provide information from Program committees and panels for Laboratory Center implementation of approved standardized procedures

b. Develop and implement methodology to:

1) Assign Laboratory Center workload (samples from applicants) after recommendation by the Evaluation Panel and NHLBI approval. The assignments shall maximize throughput and effectiveness in each Laboratory Center and for the RS & G Program overall. The Coordinating Center shall maintain communications with the Laboratory Centers to result in no downtime attributable to the assignment process.

2) Track and report assigned work and accomplished work at each Laboratory Center and for the Laboratory Centers overall.

3) Receive production, quality control, and other information as needed for the committees, panels, and Coordinating Center to fulfill their functions in the RS & G Program.

5. Develop and implement effective and efficient communication and operational interfaces with NHLBI. Keep NHLBI informed by communicating frequently and regularly. Promptly identify to NHLBI any concerns or barriers to performance, thus permitting prompt solutions and maximum effectiveness.

   a. Forward for NHLBI approval, from the committees, panels, and Coordinating Center, recommendations for:

      1) Standardization of procedures, communication formats, etc for the Coordinating and Laboratory Centers.
      2) Applicant priority recommendations from the Evaluation Panel
      3) Procedures and timelines for posting information on the web site
      4) Review comments and recommendations from the Oversight Committee regarding performance of each Laboratory Center and of the Coordinating Center
      5) Recommendations regarding trends in the science that might suggest changes in the direction for the RS & G Program.

   b. Implement or forward NHLBI approvals or required revisions to the relevant RS & G component(s).

   c. Submit quarterly progress reports.

6. Develop and implement an effective and efficient management information system that tracks samples, quality control, and workload assignments, and provides useful, accurate, and timely reports on program status to NHLBI and to all components of the RS & G Program.

7. Ensure effective and accurate communications with the DNA re-sequencing and genotyping community by applying appropriate technical/scientific expertise to Coordinating Center tasks.

**During Phase II - Pilot Testing ( Coord Center months 10 - 15)**

1. Continue the requirements from Tasks 1 - 7 of Phase I and implement the results from Tasks 1 - 7. Finalize any tasks remaining from Phase I.

2. Implement the following reporting requirements to NHLBI:

   a) Submit a monthly summary of the status of studies approved to use the services, of assigned studies, of completed studies, and on web site issues.
   b) Submit an annual technical progress report.

c) On an annual basis, propose a Performance Assessment Scheme (PAS) for the upcoming year.
d) Submit information for evaluation of performance under the PAS for the past year.

3. Develop and implement the technical assistance and information sharing aspects of the web site. The information sharing aspects of the web site shall be updated once per month. Via the web site, the Coordinating Center shall provide public access to a table listing the genes/regions that have been re-sequenced, contact information for the investigators who have used the Laboratory Center services, laboratory information such as laboratory protocols, successful primers, quality control procedures, quality control data, sample applications, help, answers to frequently asked questions, user-friendly links for reporting problems and asking questions, tutorials, site URLs or links to publicly available software for interpreting sequencing data, selecting variants for genotyping, and association analysis software packages. The site shall offer search capability by genomic region and gene name.

4. Continuously seek and recommend ways to improve the performance by the Administrative Coordinating Center and by the RS & G Program. Maintain a partner-focused cooperative working relationship with the Laboratory Centers, all committees/panels, and NHLBI.

**During Phases III, Regular Production, and IV, High Production, (Coord Center months 16 - 60)**

1. Continue the requirements of Tasks 1 - 7 of Phase I and Tasks 1 - 5 of Phase II. Finalize any tasks remaining from Phases I or II.

2. Maintain all databases, web site, software, and services in a manner that can be readily transitioned to another provider, to ensure continuity of service in the event of contract termination or upon contract re-competition. Cooperate with NHLBI and the new provider in the event of transition to a new provider.

3. Submit the final report and all products developed under the contract.

**D. Human Subjects**

No research involving human subjects will be required of the Administrative Coordinating Center. However, each investigator wishing to use the RS & G program must provide approval from their Institutional Review Board for the requested service. Further, each Laboratory Center must be approved for handling human DNA. It is anticipated that most Institutional Review Boards will find that exemption 4 applies to the Laboratory Centers.

## E. Special Requirements

Competition for this acquisition will be limited to those contractors holding indefinite delivery indefinite quantity contracts under the NIH Public Information and Communications Services (PICS) contracts. The PICS website is http://dssa.od.nih.gov/PICS.

## F. Estimate of Effort

The types of personnel and levels of effort identified below are estimated to be necessary for successful completion of the Administrative Coordinating Center objectives. Effort is shown as a percentage of full-time equivalent (FTE) labor. The personnel and levels of effort below are for information only and are not to be considered restrictive for proposal purposes.

| Labor Category | Phase I | Phase II | Phase III | Phase IV |
|---|---|---|---|---|
| Principal Investigator | 50% | 50% | 50% | 50% |
| Assistant to PI | 100% | 100% | 100% | 100% |
| Subject Matter Expert | 5% | 5% | 5% | 5% |
| Computer Specialist | 75% | 75% | 75% | 75% |
| Web Designer | 25% | 25% | 10% | 10% |
| Programmer | 25% | 25% | 20% | 20% |
| Secretary | 100% | 100% | 100% | 100% |
| Total: | 380% | 380% | 360% | 360% |

**Note**: Offerors shall ensure that all personnel proposed will not be committed on Federal grants and contracts for more than a total of 100% of their time. If it is determined that a proposed individual is committed for more than 100% of his or her time, the Government will require the offeror to adjust the time commitment.

## G. Travel

During Phase I (months 1-9), PI travel will include one Steering Committee (SC) meeting in Bethesda, MD, and one in a central location such as Chicago, IL with each meeting lasting two days. In Phase II (months 10 - 15), the PI shall attend one SC meeting in Bethesda, MD lasting two days. During Phases III and IV (months 16 - 60), the PI shall attend two 2-day SC meetings per year with one in Bethesda, MD, and the other in a central location such as Chicago, IL. The Evaluation Panel and Oversight Committee meetings will be planned to coincide with these SC meetings.

## H. Past Performance

A formal review of past performance is not required for task order awards under the PICS contracts. Nevertheless, the Contracting Officer may perform a past performance review. Offerors shall submit the following information as part of their business proposal (for both the offeror and proposed major subcontractors): A list of the contracts, grants, or cooperative agreements completed during the past two years and all contracts currently in progress for products or services similar to the solicitation work scope. The list may include agreements entered into with the Federal Government, agencies of state and local governments, and commercial organizations. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts performed by all proposed key personnel. Include the following information for each contract or subcontract:

a) Name of Contracting Organization
b) Contract Number (for subcontracts, provide the prime contract number and subcontract number)
c) Contract Type
d) Total Contract Value
e) Description of Requirement
f) Contracting Officer's Name, Telephone Number, and E-mail Address
g) Project Officer's Name, Telephone Number, and E-mail Address

Offerors may be evaluated on their performance under existing and prior contracts for similar products or services. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. The Government is not required to contact all references provided by the offeror. References other than those identified by the offeror may be contacted by the Government to obtain additional information.

## I. Information Technology Systems Security Plan

The Administrative Coordinating Center will be required to submit an information technology system security plan. The Government will provide information prior to closing negotiations.

**REPORTING REQUIREMENTS**

In addition to those reports required by other terms of this contract, the Contractor shall prepare and submit the following technical progress reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract.

**Quarterly Progress Report:** This report shall document and summarize all work results for the period covered. The Quarterly Progress Report shall be in sufficient detail to explain comprehensively the results achieved. The text shall be in letter form (up to five pages) and submitted to the NHLBI Contracting and Project Officers. The report shall include progress for the quarter, problems encountered during the quarter, a discussion of each Key Performance Requirement in the PAS, and a summary of activities planned for the next quarter. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. A Quarterly Progress Report is not required for the periods in which an Annual Report or the Final Report is due.

**Annual Progress Report:** This report shall document and summarize all work results for the period covered with a specific section to cover the last quarter's progress. Specifically, the Annual Progress Report shall include:

1. Cover page to include contract number, title, period of performance being reported, Contractor's information (name, address, telephone and facsimile numbers, e-mail address), and date of submission;

2. Description of overall progress including the intended work for the reporting period and the work that was completed;

3. Current problems which may impede performance and proposed corrective actions;

4. The advancements made in relation to any of the technical tasks;

5. Problems (technical or financial ) that occurred during the current reporting period and their resolution or status.

**Performance Assessment Reporting**

1. Detailed information for the evaluation using the Performance Assessment Scheme for the past year; and

2. Recommendations for the Performance Assessment Scheme for the upcoming year.

**Final Report:** This report shall consist of a summation of the work performed and results obtained for the entire contract period of performance. The Final Report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period.

## PACKAGING AND MARKING

All deliveries required under this contract shall be packaged, marked, and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## INSPECTION AND ACCEPTANCE

Review of Deliverables or reports shall be performed by the Project Officer and/or RS & G Program entity.

As the authorized representative of the Contracting Officer, the Project Officer will perform inspection and acceptance of materials and services.

The Government will respond promptly to inquiries from RS & G Program contractors and will provide comments on drafts no later than15 working days after delivery of the draft documentation. In the event the Government does not meet its 15 working day timeline, the Contractor may request relief under the Excusable Delays provision of the contract.

**DELIVERIES**

Administrative Coordinating Center

Satisfactory performance of the contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in SECTION C, ARTICLE C. 1., will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below, and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract:

| Item | Phase -Task # - # | Description | Quantity See Notes Below | Delivery Schedule |
|---|---|---|---|---|
| (1) | I - 1 | Draft Manual of Operations (non-lab) | * | November 15, 2004 |
| (2) | I - 1 | Manual of Operations (non-lab) | * | January 3, 2005 |
| (3) | I - 2 | Draft Minutes of Steering Committee Meetings and Calls | * | 5 working days after the meeting or call |
| (4) | I - 2 | Minutes of Steering Committee Meetings and Calls | * | 5 working days after receipt of the Project Officer's comments on the draft |
| (5) | I - 2<br>I - 5 | Draft Minutes and Recommendations from Evaluation Panel Meetings | ** | 5 working days after the meeting |
| (6) | I - 2<br>I - 5 | Minutes and Recommendations from Evaluation Panel Meetings | ** | 5 working days after receipt of the Project Officer's comments on the draft |
| (7) | I - 2<br>I - 5 | Draft Minutes and Recommendations from Oversight Committee Meetings and Calls | ** | 5 working days after the meeting or call |

| | | | | |
|---|---|---|---|---|
| (8) | I - 2<br>I - 5 | Minutes and Recommendations from Oversight Committee Meetings and Calls | ** | 5 working days after receipt of the Project Officer's comments on the draft |
| (9) | I - 3 | Proposed Marketing/Outreach Strategies/Journal Ad(s) | * | 45 calendar days after the contract effective date |
| (10) | I - 3 | Proposed Design for Exhibit Booth | * | 45 calendar days after the contract effective date |
| (11) | I - 3 | Exhibit Booth | 1<br>Notes N/A | December 15, 2004 |
| (12) | I - 3 | Detailed Plans for Web Site, Outreach & Processing Aspects | * | 45 calendar days after the contract effective date |
| (13) | I - 3 | Operational Web Site, Outreach and Processing Aspects | 1 Notes N/A | November 15, 2004 |
| (14) | I - 1<br>I - 3 | Proposed Application Policies, Procedures, and Formats | ** | 60 calendar days after the contract effective date |
| (15) | I - 3 | Application Policies, Procedures, and Formats | ** | 15 calendar days after Steering Committee acceptance |
| (16) | I - 4<br>I -5 | Proposed Policies, Procedures, and Formats for Communications with RS & G Laboratory Centers | ** | 60 calendar days after the contract effective date |
| (17) | I - 4<br>I - 5 | Policies, Procedures, and Formats for Communications with RS & G Laboratory Centers | ** | 15 calendar days after Steering Committee acceptance |

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|---|---|---|---|---|
| (18) | II - 1<br>III & IV - 1 | Quarterly Progress Reports | Notes<br>N/A | Each March 31, Sept 30, and December 30 with the first report due September 30, 2004. |
| (19) | II - 2<br>III - 1 | Annual Progress Reports | Notes N/A | Each June 30, starting June 30, 2005 |
| (20) | II - 3 | Detailed Plans for Web Site - Information Sharing and Tech Assistance Aspects | * | August 15, 2005 |
| (21) | II - 3 | Web Site becomes operational for- Information Sharing and Tech Assistance Aspects | Notes N/A | September 30, 2005 |
| (22) | I - 6<br>II - 2 | Monthly Summary of Status | * | The 10 th of each month starting June 10, 2005 |
| (23) | III - 2<br>IV - 2 | Software and documentation, for Web Site and Services | Notes N/A | On request of the Project Officer; and at the end of the contract |
| (24) | III & IV - 2 | Draft Final Report | Notes N/A | 60 calendar days before the expiration date of the contract |
| (25) | III & IV - 2 | Final Report | Notes N/A | On or before the expiration date of the contract |
| (26) | II - 2 | Report for Evaluating Performance under the Performance Assessment Scheme | Notes N/A | Each September 1 starting September 1, 2005 |
| (27) | II - 2 | Proposed Performance Assessment Scheme for the Upcoming Year | Notes N/A | Each September 1 starting September 1, 2005 |

One paper copy of each item shall be delivered to the Project Officer (PO) and one paper copy of each item shall be delivered to the Contracting Officer (CO).

Notes:
In addition to the quantities for PO and CO delivery, items noted with * must be delivered to RS & G Prinicpal Investigators . Items noted by ** must be delivered to committee and/or panel members and to the Principal Investigators.

* The total quantity is dependent on the actual number of RS & G Laboratory Centers and the submission method. The acceptability of electronic copies will be determined at the first Steering Committee meeting. As determined by the Steering Committee, each Laboratory Center will receive either one paper copy or an electronic copy.

** The total quantity is dependent on the submission method, the actual number of committee or panel members, and the actual number of RS & G Laboratory Centers. The acceptability of electronic copies will be determined at the first meeting of each committee/panel.

The NHLBI Project Officer and Contracting Officer copies of the above items shall be addressed and delivered to:

Project Officer
RS & G Program
Division of Heart and Vascular Diseases
NHLBI, NIH
6701 Rockledge Drive
Rockledge Two, Room 10184, MSC 7956
Bethesda, MD 20892-7956

Contracting Officer
RS & G Program
Contracts Operations Branch, DEA
NHLBI, NIH
6701 Rockledge Drive
Rockledge Two, Suite 6018, MSC 7902
Bethesda, MD 20892-7902

## EVALUATION CRITERIA/METHOD OF REVIEW

Through this Request for Task Order Proposal NHLBI seeks one Administrative Coordinating Center. Selection of a task order contractor will be based on evaluation of proposals against the following factors in order of importance: technical (which encompasses experience and past performance) and cost/price. Technical evaluation factors will be more important than cost/price. However, the trade-off process described in FAR 15.101-1, Best Value Continuum, will be employed. This process permits trade offs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award to obtain the best value for the Government.

## TECHNICAL EVALUATION CRITERIA

Technical evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria are listed below in the order of relative importance.

| | FACTOR | WEIGHT |
|---|---|---|
| 1. | TECHNICAL APPROACH | 40 |

The soundness, practicality, and feasibility of the approach to perform the following functions:

Facilitation: Suitability and adequacy of the offeror's plan for overall Program facilitation and coordination, and administrative leadership of all Program components.

Web Site: Suitability and adequacy of the offeror's plans for web site development and updates including functionality, timeline, security, and ease of use.

Research community interactions: Suitability and adequacy of the offeror's plan for outreach/promotion. Suitability and adequacy of the offeror's plan for receiving and processing applications from investigators.

Management Information System: Suitability and adequacy of the offeror's plan for useful, timely and accurate reports on all aspects of the Program.

2. PERSONNEL 30

Expertise, experience and availability of key personnel in supporting the planning and implementation of the Administrative Coordinating Center. Evidence of prior experience with relevant projects. Appropriate organizational experience related to the work outlined in the RFTOP, including managing projects of similar size, content and scope.

Expertise and experience in providing leadership and problem solving; providing logistical support for meetings and calls; designing, building, evaluating, and maintaining web sites; writing minutes, manuals, and brochures; and designing exhibit booths. Ability to identify and utilize technical expertise in re-sequencing and genotyping to accomplish Coordinating Center tasks.

3. MANAGEMENT PLAN 20

Adequacy of the proposed management plan, which should show clear lines of authority and responsibility, and quality control procedures to assure project goals are met in a timely manner. Adequacy of the plan for maintenance of continuity in the event of changes in key personnel.

4. FACILITIES AND EQUIPMENT 10

Availability and adequacy of facilities and equipment to perform the work.

## CONSORTIUM COMMITTEES

Consortium Committees

The **Steering Committee** will consist of the Principal Investigator from each Laboratory Center and from the Administrative Coordinating Center, and the NHLBI Project Officer. During Phase I, the Steering Committee will meet twice and hold monthly conference calls to develop common guidelines and procedures for use in all Laboratory Centers and for the RS & G Program as a whole. Following approval by NHLBI, Laboratory Centers shall implement the approved common guidelines and procedures. During Phase II, the Steering Committee will meet once and conduct teleconferences monthly. In Phases III and IV, the Steering Committee will meet twice per year and hold monthly conference calls. In all phases, the Steering Committee will be responsible for advising NHLBI on RS & G Program status, providing suggested changes to accomplish stated time, accuracy, and capacity goals, and recommending ways to improve the RS & G Program's cost efficiency. If needed, subcommittees of the Steering Committee will be established. Each participating center will have one vote.

The **Oversight Committee** will be composed of four to five expert scientists from outside the RS & G Program plus the NHLBI Project Officer. The Oversight Committee may be enlarged permanently or on an ad hoc basis as needed. The areas of expertise will include but are not limited to high-throughput sequencing and genotyping, QC, heart, lung, blood, and sleep disorders, population genetics, quantitative genetics, and related disciplines such as biostatistics, molecular genetics and genomics. The NHLBI will determine the expert scientists to serve on the Oversight Committee after obtaining suggestions from the Steering Committee, the Evaluation Committee, and other experts outside the RS & R Program. Approximately twice per year the Oversight Committee will review and evaluate performance of the Laboratory Centers and the Administrative Coordinating Center and make recommendations to the NHLBI regarding management of the RS & G Program. During the first year (Phases I and II), the Oversight Committee will meet face-to-face twice. For the following years (Phases III and IV), the Oversight Committee will meet once a year and conduct a conference call for the second evaluation. The PI for each Laboratory Center will attend Oversight Committee meetings. Each Laboratory Center will provide requested information in a timely manner. The Oversight Committee shall review Laboratory Centers for QC, success in maintaining state of the art, readiness for and implementation of technology improvements, success in the R&D activities of the Laboratory Center, success in meeting targets for increasing capacity and productivity, and overall performance against each Laboratory Center's Performance Assessment Scheme (Quality Assurance Surveillance Plan). The Oversight Committee shall review the Administrative Coordinating Center regarding its success in meeting its objectives regarding distribution of projects in a timely manner to facilitate the optimum functioning of the Laboratory Centers; logistical support for the panels and committees; acceptance, functionality, and use of the web site and databases; and overall performance against the Administrative Coordinating Center's

Performance Assessment Scheme.

The **Evaluation Panel** will comprise six expert scientists from outside the RS & G Program plus the NHLBI Project Officer in Phases I and II. The size of the Evaluation Panel will expand up to twelve members by the third year in concert with increased Laboratory Centers' capacity and productivity. The NHLBI will determine the members of the Evaluation Panel after consultation with the Steering Committee and experts from outside the NHLBI and the RS & G Program. In Phase I, the Evaluation Panel will establish the review criteria and the application form. During Phases II-IV the Evaluation Panel will review requests from investigators for resequencing or genotyping services and make recommendations, in priority order, regarding studies to be authorized to use the services in the upcoming period. The objective of the review is to ensure that the Laboratory Centers provide these services to the most meritorious, high caliber genetic studies focused on finding genes associated with a disease or trait of interest. The review will consider each request regarding programmatic priority, feasibility, adequacy of the size and power, and cost. Only investigators with a justifiable amount of resequencing or genotyping will be selected for the Program. The Evaluation panel also will make sure that the applicant proposals involving human subjects are in compliance with NHLBI guidelines and policies as per http:// www.nhlbi.nih.gov/funding/policies and that they include the necessary approvals from the investigator's Institutional Review Board.

## UNIFORM COST ASSUMPTIONS

Uniform Cost Assumptions
Administrative Coordinating Center
for NHLBI DNA Re-sequencing and Genotyping Program

These Uniform Cost Assumptions supplement the "boilerplate" technical and business proposal instructions located elsewhere in this RFTOP. These assumptions provide specific guidance on tasks and costs that should be considered in preparing the technical and business proposals.

**General**

Through this Request for Task Order Proposal (RFTOP HV 04 -12), NHLBI seeks one contractor for an Administrative Coordinating Center (Coordinating Center) for the NHLBI DNA Re-sequencing and Genotyping Program (RS & G Program). In addition to the Coordinating Center, the RS & G Program will comprise one to two DNA Re-sequencing Centers and one to three Genotyping Centers. Fewer Laboratory Centers may be awarded based on the capacity of offerors and the need for services. The Laboratory Centers will service NHLBI and other approved investigators (applicants) at no cost to the investigator. The Laboratory Centers will be selected through a competitive procurement separate from this RFTOP. The Laboratory Centers RFP may be viewed at NHLBI's web site http://www.nhlbi.nih.gov/funding/inits/index.htm#rfp.

It is anticipated that Administrative Coordinating Center performance will begin June 1, 2004 and that the Laboratory Centers will begin performance no later than September 1, 2004. The Coordinating Center will make arrangements for the first Steering Committee meeting to be held promptly (assume no later than two weeks) after Laboratory Center performance begins.

For **Cost Proposal purposes**, assume:

1. The Cost Proposal shall be prepared by phases, with Phase I from June 1, 2004 through February 28, 2005, and Phase II from March 1, 2005 through August 31, 2005. Options shall be proposed for Phases III and IV, as follows:

   Option 1: September 1, 2005 through April 30, 2006
   Option 2: May 1, 2006 through May 31, 2009

   Show costs for Option 2 by the following periods:

   May 1, 2006 through August 31, 2007
   September 1, 2007 through August 31, 2008
   September 1, 2008 through May 31, 2009

2. The Cost Proposal shall be submitted electronically as well as in hard copy (an

original and four copies.) The electronic proposal shall use the spreadsheet as available at http://ocm.od.nih.gov/contracts/rfps/buscost.htm. It may be submitted by e-mail to Betty Nordan at Betty Nordan@nih.gov or by diskette enclosed with the paper copies.

3. Estimating Meeting Costs

a) The Steering Committee will consist of the Principal Investigator from each Laboratory Center and from the Coordinating Center, and an NHLBI representative, at 4 to 7 voting members. The Steering Committee will hold monthly conference calls except during months when the Committee meets. The Administrative Coordinating Center should budget for conference call costs. Additionally, the Steering Committee will meet three times in the first year and twice per year each year thereafter. Meeting locations will be determined after award. For estimating purposes, assume one meeting each year will be in the metropolitan Washington, DC area and one meeting each year will be in a central location such as Chicago, IL. Except for costs for Coordinating Center staff (three maximum in Year 1 and two maximum thereafter), travel and hotel costs will be supported outside this task order award. Assume that each meeting will require a two-night hotel stay.

b) Oversight Committee: Budget for four external experts. The NHLBI Project Officer will also be a member, but Project Officer travel costs will be supported outside this task order award. The task order award will provide honorarium financial support to the external experts, and reimburse the experts for their travel expenses to the meetings. Assume the committee will meet once each year and will hold one conference call review each year. Meeting locations will be determined after award. For estimating purposes, assume the meeting each year will be in the metropolitan Washington, DC area. Assume that each meeting will require a one-night hotel stay. Assume that the honorarium to the external experts will be $200 per day for the on site meeting and $100 per day for the conference call. Assume that Laboratory Center Principal Investigators will attend Oversight Committee meetings, with their costs supported outside this task order award. Budget for attendance by one person from the Coordinating Center.

c) The Evaluation Panel: Budget for 6 to 12 external experts [Year 1 - 6; Year 2 - 10; Year 3 - 12; Year 4 - 12; Year 5 - 12]. The NHLBI Project Officer will also be a member, but Project Officer travel costs will be supported outside this task order award. The task order award will provide honorarium financial support (assume $200 per day) to the external experts, and reimburse the experts for their travel expenses to the meetings. Assume the Panel will meet twice each year. Meeting locations will be determined after award. For estimating purposes, assume one meeting each year will be in the metropolitan Washington, DC area and one meeting each year will be in a central location such as Chicago, IL. Assume that each meeting will require a two- night hotel stay. Assume that Laboratory Center Principal Investigators will attend Evaluation Panel meetings, with their costs

supported outside this task order award. Budget for attendance by two people from the Coordinating Center.

Assume the first Evaluation Panel meeting will be a joint session with the Steering Committee, to allow the two groups to interact directly with each other. Objectives at the first Evaluation Panel meeting are to set review standards and procedures, to develop an application format for requests for services, and to review and prioritize at least one set of requests for laboratory centers use.

See Consortium Committees, for additional information on committees and panels.

4. Estimating Equipment Costs

   Assume that the task order award will provide funds to purchase one server for the web site. It is expected that other equipment and facilities will be provided by the Coordinating Center contractor.

5. Estimating Promotion/Outreach

   Assume that promotion/outreach will focus on electronic methods, advertising, and a manned exhibit (two people) at national meetings each year throughout the performance period. Budget for the following numbers of national meetings: Year 1: 2 meetings; Years 2, 3, & 4: 5 meetings /year; Year 5: 1 meeting. Assume that commercial exhibit space rather than Government-rate exhibit space will be rented.

   Assume that advertisements will be placed in eight journals twice per year in years 1, 2, and 3 and in five journals twice per year in years 4 and 5.

6. Assume that requests from investigators to use the Laboratory Center services will be received twice each year. Electronic submission will be mandatory.

7. Per the terms and conditions of the NIH Public Information and Communications Services contracts, under the Task Order, reimbursement for travel expenses shall be allowable only to the extent the expenses do not exceed the amount allowed for Federal employees. Do not budget for the Project Officer's travel costs.

**RFTOP# 151 TITLE: Administrative Coordinating Center for the NHLBI DNA Re-sequencing and Genotyping Program HV-04-12**

PART II–CONTRACTOR'S REPLY: CONTRACT #263-01-D-0____
TO# NICS-_____

Contractor:
Points of Contact:
Phone: Fax:
Address:

TOTAL ESTIMATED COST: Pricing Method:Cost-Reimbursement
TOTAL ESTIMATED NUMBER OF HOURS:
PROPOSED COMPLETION DATE:

FOR THE CONTRACTOR: _____
Signature Date

==========

**SOURCE SELECTION:**

WE HAVE REVIEWED ALL SUBMITTED PROPOSALS AND HAVE DETERMINED THIS FIRM SUBMITTED THE BEST OVERALL PROPOSAL AND THE PRICE/COST IS REASONABLE:

Billing Reference # _____

Appropriations Data: _____
(ATTACH OBLIGATING DOCUMENT IF A ROC WILL NOT BE USED)

RECOMMENDED: _____
FAX # Signature–Project Officer Date

APPROVED: _____
FAX # Signature–Contracting Officer Date

_____

**NIH APPROVAL--**

CONTRACTOR SHALL NOT EXCEED THE ESTIMATED LABOR HOURS OR ESTIMATED TASK ORDER AMOUNT WITHOUT THE WRITTEN APPROVAL OF THE CONTRACTING OFFICER AND ICS COORDINATOR

APPROVED: _____
Signature–Anthony M. Revenis, J.D., NIH ICS Coordinator Date