

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID NO.	PAGE OF PAGES 1   3
2. AMENDMENT/MODIFICATION NO. 004		3. EFFECTIVE DATE Oct 27, 2003	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)	
6. ISSUED BY National Institutes of Health National Heart, Lung, and Blood Institute Rockledge II, Room 6114 6701 ROCKLEDGE DR MSC 7902 BETHESDA MD 20892-7902		CODE	7. ADMINISTERED BY (if other than Item 6)		CODE
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) Recipients of RFP-NHLBI-HV-04-13 "Laboratory Centers for the NHLBI DNA Re-sequencing and Genotyping Program"				( <input checked="" type="checkbox"/> ) 9A. AMENDMENT OF SOLICITATION NO. RFP-NHLBI-HV-04-13	( <input checked="" type="checkbox"/> ) 9B. DATED (SEE ITEM 13) August 14, 2003
CODE				10A. MODIFICATION OF CONTRACT/ORDER NO.	
FACILITY CODE				10B. DATED (SEE ITEM 13)	

11. THIS ITEM APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offers is extended,  is not extended.

Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning \_\_\_\_\_ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR 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, the change must 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 in the solicitation.

12. ACCOUNTING AND APPROPRIATION DATA (if required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

() A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. \_\_\_\_\_

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: \_\_\_\_\_

D. OTHER (Specify type of modification and authority) \_\_\_\_\_

E. IMPORTANT: Contractor  is not,  is required to sign this document and return \_\_\_\_\_ copies to the issuing office.

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

Recently received inquiries are discussed on the following pages concerning RFP-NHLBI-HV-04-13, Laboratory Centers for the NHLBI DNA Re-sequencing and Genotyping Program.

A picture of the Contracting Officer's signature is omitted from Block 16B. of this amendment to reduce the file size.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Betty Nordan Contracting Officer, WHI Contracts Team	
15B. CONTRACTOR/OFFEROR  (Signature of person authorized to sign.)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY <u>Betty Nordan</u> (Signature of Contracting Officer)	16C. DATE SIGNED

**The following inquiry has been received:** 1. The sentences on page 1 and later in the Statement of Work (SOW) about the total expected genotyping for the entire program can be interpreted several ways. Please clarify.

**The following response applies:** This question led us to realize there is a typo in the SOW about the expected genotyping for the entire program. The second paragraph on page 1 states 10 genes per year with approximately 10 SNPs per gene in an average of 2000 individuals. The statement should have read 100 genes. The RFP correctly stated that, at contract award, each genotyping center is expected to produce 500,000 genotypes per year. The correct information follows:

The RS & G Program's initial genotyping effort (sum of all Genotyping Centers) is expected to be capable of customized genotyping of at least 100 genes per year with approximately 10 single nucleotide polymorphisms (SNPs) per gene in an average of 2,000 individuals. Thus, the total program effort is expected to be 2 million genotypes per year. Each Genotyping Center will generate at least 500,000 genotypes per year with an error rate of no more than 1%.

**The following inquiry has been received:** 2. Please clarify the expected number of genotypes to be generated per genotyping center during the four phases of the contract.

**The following response applies:**

- Phase I Be able to perform at least 500,000 per year (2 million per year for the entire genotyping program) Genotyping could be performed as part of protocol development, but no production genotyping is planned in the phase.
- Phase II At least 250,000 during this six month phase.
- Phase III 500,000 plus per year.
- Phase IV 1 million per year (4 million per year for the entire genotyping program).

**The following inquiry has been received:** 3. Please clarify the per unit cost expectations by phase for the genotyping centers.

**The following response applies:**

- Phase I and II No more than an average cost of \$1.50 per genotype.
- Phase III Less than an average cost of \$1.50 per genotype.
- Phase IV No more than an average cost of \$0.75 per genotype.

**NOTE: It is expected that the contracts will be awarded on a cost reimbursement basis. However, costs will be tracked on a per unit basis as well.**

**The following inquiry has been received:** 4. Please clarify the requirement in the Mandatory Qualification Criteria that "At award of the contracts...each genotyping center will generate at least 500,000 genotypes per year..."

**The following response applies:** The requirement is intended to convey that NHLBI is seeking genotyping centers that are experienced as a high throughput center rather than as a laboratory for customized work only. Your proposal must document your experience as a high throughput center. The RFP permits until "award of the contract", which is anticipated for August 31, 2004, to meet the stated requirement.

***The following inquiry has been received:*** 5. Will the genotyping centers perform on genotyping rats and mice in addition to human samples?

***The following response applies:*** The program is intended to meet the need for genotyping of human samples. However, if capacity under the program is in excess of that needed for human samples, genotyping on other mammals could be required.

***The following inquiry has been received:*** 6. The RFP is unclear in its statement about estimated labor hours (page 13 in the Statement of Work). Please clarify.

***The following response applies:*** The estimate for labor hours should not be considered restrictive for proposal purposes. We are seeking the offeror's realistic estimate of labor mix and hours for the required work.

***The following inquiry has been received:*** 7. Are there any constraints on the amount that may be proposed as fee? How does NIH determine an appropriate fee?

***The following response applies:*** The Federal Acquisition Regulation, at Part 15.404-4, specifies 10% of proposed costs as the maximum fee for other than R&D and 15% as the maximum fee for R&D contracts. This work is considered R&D. In negotiating a fixed fee, NIH contract specialists commonly use Form HHS 674, Structured Approach, Profit/Fee Objective.

***The following inquiry has been received:*** 8. How much time should I allot for X-ray screening of the proposal after the boxes arrive at the Rockledge site?

***The following response applies:*** We are unable to give an estimate because the time will vary with the number of proposals and other variables beyond our control.

***The following inquiry has been received:*** 9. Has the deadline for proposals been extended?

***The following response applies:*** The deadline for proposals remains Wednesday, November 5, 2003, at 4:30 pm local time.