RFP No. NHLBI-HB-04-28

"Maintenance of NHLBI Cord Blood Units"

Request for Proposal No.:	**NHLBI-HB-04-28**
Issue Date:	**March 15, 2004**
Issued By:	**Lynda A. Bindseil, Contracting Officer** **NIH/NHLBI** **Contracts Operations Branch** **6701 ROCKLEDGE DR MSC 7902** **BETHESDA MD 20892-7902**
Purchase Authority:	**42 USC 201 Public Health Service Act of 1944, as amended**
Small Business Set-Aside:	**No; NAICS 621991**
Proposal Intent Date:	**April 7, 2004**
Proposal Due Date:	**May 4, 2004, 4:00 P.M. (Eastern Time)**

Ladies and Gentlemen:

The National Heart, Lung, and Blood Institute (NHLBI) is soliciting proposals to transfer the Cord Blood Transplant (COBLT) Study Cord Blood Banks (CBBs) located at Duke University Medical Center and the University of California at Los Angeles to two (2) acceptable Cord Blood Bank programs. The NHLBI anticipates that two (2) **no cost contracts** will be awarded for a period of 10 years.

This Streamlined Technical Request For Proposal (RFP) consists of this combined solicitation form and cover letter (PART A), and four additional components, as follows:

B. Objectives/Background Information/Technical Requirements/Proposal Requirements;
C. Reports/Deliverables;
D. Evaluation Factors for Award with Technical Evaluation Criteria
E. Attachments (Equipment and FAR Clauses)

These components contain the technical information required for the submission of a proposal for this acquisition. In addition, there are two other sections in this specific RFP. The section entitled "Specific RFP Instructions and Provisions" contains, for example, the address for delivery of your proposal. The section entitled "Applicable RFP References" lists those items in the STREAMLINED RFP REFERENCES directory that apply to this RFP, including forms for submission of the proposal. The Streamlined RFP References directory is located at URL:

http://ocm.od.nih.gov/contracts/rfps/Techinst1.htm

Although these documents contain sufficient information for you or your organization to submit a proposal, if you intend to submit a proposal in response to this RFP, IT IS ESSENTIAL THAT YOU IMMEDIATELY NOTIFY LYNDA A. BINDSEIL, CONTRACTING OFFICER, AT THE FOLLOWING INTERNET ADDRESS: bindseil@nhlbi.nih.gov

IF YOU DO NOT NOTIFY THE CONTRACTING OFFICE OF YOUR INTENT TO SUBMIT A PROPOSAL, YOU WILL NOT RECEIVE AN INDIVIDUAL NOTICE OF ANY AMENDMENTS TO THE RFP, IF ANY ARE ISSUED. HOWEVER, ALL AMENDMENTS

WILL BE POSTED ON THE NIH WEB SITE.

An original and twelve (12) copies of your technical proposal and one (1) original business proposal must be received by the Contracting Office no later than **May 4, 2004, 4:00 P.M. (Eastern Standard Time)** at the address listed in the item entitled "Packaging and Delivery of Proposals". Also, please complete the form entitled "**Proposal Intent Response Sheet**" and send it to the address indicated therein on or before **April 7, 2004.** This will allow us to expedite preparations for the review of proposals. Your proposal must be organized and submitted in accordance with the "Technical Proposal Table of Contents." These items are found under the "Specific RFP Instructions and Provisions" portion of this RFP, which follows the technical evaluation criteria section.

You are reminded that the "Technical Proposal Cover Sheet" must be completed in full detail and used as the cover sheet for each copy of your technical proposal. (This form is contained in this NIH WEB site under the FORMS, FORMATS, AND ATTACHMENTS. This information will be used to ensure that there will be no conflict of interest when selecting review committee members.

Contracts awarded under this solicitation will be **"no cost contracts"** with a **fixed-price of $0**. The "Proposal Summary and Data Record, NIH 2043" also located at the site for FORMS, FORMATS, AND ATTACHMENTS shall be included in the business proposal along with other requested business-related materials. Since Government funding will not be provided, many of the standard FAR clauses typically pertinent to Government contracts, will not be applicable. However, certain clauses will apply and become part of any resultant contract. A list of potential clauses are included as an attachment to this RFP.

NOTE: IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH PHSAR CLAUSE 352.215-10.

SUBMISSION OF PROPOSALS USING FACSIMILE OR E-MAIL IS NOT AUTHORIZED.

If you have any additional questions regarding this RFP, please contact Ms. Lynda A. Bindseil through the Internet using the electronic mail address bindseil@nhlbi.nih.gov, or phone (301) 435-0356 by or before April 7, 2004. Collect calls will not be accepted.

Sincerely,
/s/
Ms. Lynda A. Bindseil
Contracting Officer

B. WORK STATEMENT

a. Objectives

The objectives of this project are to transfer the Cord Blood Transplant (COBLT) Study Cord Blood Banks (CBBs) located at Duke University Medical Center (DUMC), Durham, North Carolina, and the University of California at Los Angeles (UCLA), California to two acceptable CBB programs and ensure 1) eligible COBLT cord blood units (CBUs) are made available for clinical use, 2) the requirements of the donor informed consent document are adhered to, 3) eligible COBLT CBUs are listed in the National Bone Marrow Donor Registry, and 4) transplant infusion and outcome data are made available to a national data registry.

b. Background Information

The National Heart, Lung, and Blood Institute (NHLBI) funded COBLT banking program was initiated in 1996 and conducted under a Food and Drug Administration (FDA) accepted Investigational New Drug (IND) application. The program included three banks, multiple collection centers, a CBB committee, and a medical coordinating center. The overall goal of the program was to build ethnically diverse CBBs using standardized procedures for the collection, testing, processing, cryopreservation, and thawing of unrelated donor umbilical cord blood to support an umbilical cord blood transplantation protocol. The procedures included an informed consent process requiring education of the donor (baby's mother) regarding cord blood banking and transplantation and the signing of an informed consent document. The document included information on infectious disease testing of maternal blood samples, the storage of the CBU, possible additional testing of stored cord blood and maternal samples, and maintaining donor confidentiality. The link between the donor and the CBU was kept in a restricted access data base at the CBB. Full details of the procedures can be found in the COBLT CBB Standard Operating Procedures at http://www.emmes.com.

Cord blood collections were initiated in December 1997 and continued through June 2001. Over 8,000 CBUs were cryopreserved and determined eligible as a stem cell source following a double review of source documentation by CBB staff and a data review by the COBLT computer algorithm. Approximately 280 CBUs with a maternal blood sample with a negative Hepatitis B surface antigen test, positive Hepatitis B core antibody test, a negative maternal serum Hepatitis B nucleic acid test, and negative cord blood plasma Hepatitis B nucleic acid test, and meeting all other eligibility criteria, are stored separately because their use is under discussion with the FDA.

Eligible units have been Human Leukocyte Antigen (HLA) typed. Cryopreserved CBUs, including CBUs stored for quality assurance, are stored in liquid nitrogen freezers (UCLA: large stainless steel automatically filling storage freezers; DUMC: Thermogenesis Bioarchive® System) in 25 mL bags (MedSep). Granulocyte/red cell pellet, plasma, and serum samples associated with each CBU are stored in -80^0C and -20^0C mechanical freezers and viable cord blood samples are stored in liquid nitrogen freezers. Electronic data bases with confidential donor information, CBU characterization data, and HLA typing information and computer software necessary to operate the bank will be provided to the contractor. Source documentation for the collection, processing, characterization, and infectious disease testing of each unit will be provided in labeled paper files.

c. Technical Requirements

[PLEASE NOTE: Your proposal will be for the contents and equipment associated with one (1) cord blood bank. The Government reserves the right to determine which bank will be provided to the two (2) successful offerors.]

Phase I: **Moving of COBLT CBUs and Government Furnished Property**

The contractor, in collaboration with NHLBI and COBLT CBB staff, shall coordinate an orderly and safe transition of one of the COBLT CBBs from the current contractor site to the new location. The transfer will include the transport of stored cord blood units, specimens, source documentation, electronic data files, and all eligible Government furnished property. Temperature monitoring will be conducted throughout the transfer process to ensure all CBUs are maintained within an acceptable temperature range. Relocation costs from the current CBB locations at Duke University Medical College, Durham, North Carolina and the University of California, Los Angeles, Los Angeles, California will be funded under existing contracts.

[For solicitation purposes: a plan for this transition phase must be included in the proposal. The plan shall include a time line for the physical relocation of the liquid nitrogen and mechanical freezers containing the CBUs and associated samples, electronic data files, and paper files containing source documentation from one of the existing contractor sites to the offeror's facility. A current list of eligible Government-owned equipment and items to be transferred from the DUMC and UCLA CBBs can be found in Attachments 1 and 2. **]**

[Note to offerors: In the event an incumbent contractor submits an acceptable proposal that is subsequently selected for contract award, all equipment at that particular site shall remain at that site.**]**

Phase II: **CBB Management and Operation**

Task 1 - Facilities to Store CBUs, Associated Samples and Source Documentation

The contractor shall provide facilities and all necessary equipment and resources not otherwise provided by the government to store COBLT CBUs; associated serum, plasma, granulocyte/red cell pellet and viable CBU samples; electronic data bases; and paper files containing source documentation. The freezers containing CBUs and associated samples; and electronic databases, computer software and paper files with source documentation will be supplied to the contractor. CBUs designated eligible as a stem cell source will be stored in the liquid phase of liquid nitrogen. CBUs stored for quality assurance (QA) testing and viable cord blood samples will be stored in either the liquid or vapor phase of liquid nitrogen. Associated CBU samples shall be maintained in mechanical freezers at temperatures of -20^0C or lower. The contractor shall supply acceptable temperature controlled facilities and uninterruptible power to accommodate the freezers and other equipment. Freezers shall be connected to a central alarm system monitored twenty-four hours a day. The contractor shall provide an automated temperature monitoring system composed of individual temperature probes monitored 24 hours a day and controlled by a master computer, and a plan to ensure that necessary personnel are notified in the event of freezer malfunction. Sufficient emergency standby freezers must be available in case of mechanical failure of any portion of storage space. In addition, alternative emergency freezer cooling systems such as a liquid nitrogen system or dry ice shall be available. The contractor must have backup electric generators capable of maintaining the CBUs and associated samples, for as long as necessary, in the event of utility company power failure.

[For solicitation purposes: currently there are approximately 4,000 eligible, HLA typed COBLT CBUs stored at each CBB. A current list of eligible Government-owned equipment and items to be transferred

from the DUMC and UCLA CBBs can be found in Attachments 1 and 2. All future equipment needs will be the responsibility of the contractor without financial support under the contract. **]**

[Note to offerors: The proposal must provide a detailed floor plan of the proposed facility showing location of the equipment and resources and square feet of space available. Offerors shall include information on the resources and the engineering features that will be used to maintain the CBU liquid nitrogen freezers, associated sample mechanical freezers, electronic data bases, and paper files containing source documentation. Offerors must specify if their facilities are or will be adequate to house and maintain Thermogenesis Bioarchive® Systems and large stainless steel automatically filling storage freezers. If construction or renovation of space is proposed, the renovations must be described in detail and must be completed prior to contract award.**]**

Task 2 - Maintaining and Shipping COBLT CBUs

The contractor shall provide trained personnel, equipment not supplied by the government, and validated procedures for storing, retrieving and transporting cryopreserved CBUs to transplant centers when requested. The contractor shall maintain the unique COBLT CBU ISBT-128 identification number, assigned at collection, to identify each CBU, associated samples, and data files. The contractor shall ensure the terms of the donor informed consent document are adhered to and that donor confidentiality is maintained. The contractor shall review the IRB approved informed consent documents used by the COBLT CBBs to identify limitations on the use of any of the supplied units and samples and ensure these limitations are adhered to. The contractor shall require that COBLT CBUs are thawed for transplantation using validated procedures and that transplant centers agree to discard, or use for validation purposes, CBUs shipped for transplant but not used. CBUs stored for quality assurance testing, and their associated samples, may be used by the contractor for validation purposes only. Validation purposes include, but are not limited to, validation of thawing procedures at the CBB and transplant center, validation of infectious disease tests and viability testing of stored CBUs. Other uses of the quality assurance CBUs, or there associated samples, shall not be allowed under this contract. Samples associated with transplanted CBUs may be used in clinical outcome research within the limitations of the donor informed consent document. The contractor shall comply with all federal and other non-federal regulations regarding licensure, need for a Food and Drug Administration Investigational New Drug Application, maintaining and transporting CBUs. The contractor shall supply the NHLBI annually with documentation that compliance with all federal and non-federal regulations has been maintained and include copies of any reports on the COBLT CBUs.

[Note to offerors: Proposals must provide a staffing plan and a description of staff training, experience, and availability. Offerors shall include a description of the informed consent document review process and implementation of any limitations imposed by the consent. Offerors shall include a description of how CBUs will be reserved, retrieved from the bank inventory, and shipped to the transplant center. Offerors shall include a description of how the CBB inventory will be updated following shipment of a CBU. Offerors shall include a description on ensuring COBLT CBUs are thawed at the transplant center using a validated thawing procedure and that quality assurance CBUs are used for validation purposes only. Offerors shall include information on cord blood bank program accreditation by non-federal organizations and include information on procedures for complying with federal and non-federal regulatory requirements. **]**

Task 3 - Make Eligible CBUs Available to Potential Transplant Recipients

The contractor shall make COBLT CBUs determined eligible as a stem cell source by the COBLT Algorithm available to potential transplant recipients and their physicians by listing the units in the National Bone Marrow Donor Registry. The contractor may list the COBLT CBUs with other search registries if the contractor can ensure 1) that a COBLT CBU reserved for a potential recipient is removed

from all search registries at the time of reservation 2) that if a CBU reservation is cancelled prior to shipment that the CBU is returned to all registries at the time of cancellation. The contractor may charge a transplant recipient for each COBLT CBU shipped for transplantation. The fee for non-licenced use must be based on cost-recovery. The fee for licensed use may be based on the fair market value.

[For solicitation purposes, assume the following: All electronic data bases, computer software, and source documentation necessary to determine CBU eligibility and availability will be supplied to the contractor. The informed consent documents and documentation of all amendments will be supplied to the contractor. Electronic and paper files containing confidential information will also be supplied.**]**

[Note to offerors: Offerors must provide a detailed plan for listing the units in the National Bone Marrow Donor Registry. If offerors wish to list the COBLT CBUs with more than one search registry, then the reason(s) for listing the units in more than one registry shall be provided along with a detailed plan of how and when reserved units will be removed from all search registries and returned to all registries if a reservation is cancelled prior to shipment. Offerors shall provide a detailed plan of how the fee for non-licensed use will be calculated.**]**

Task 4 - Provide Transplant Outcome Data to National Data Registry

The contractor shall obtain and make available transplant infusion and post-transplant outcome data to an established national data registry. The registry chosen shall have a research agenda focused on improving options and outcomes for those in need of blood stem cell transplants.

[For solicitation purposes, assume the following: The data bases and source documentation providing pre-cryopreservation data for CBU collection, processing, cryopreservation, characterization, and testing will be supplied.**]**

[Note to offerors: Offerors shall provide a detailed plan of agreements and procedures that will be used to obtain product infusion data and post-transplant outcome data and how these data will be submitted to a national data registry. The plan shall include a description of the registry research interests and plans to address options and outcomes for those in need of a blood stem cell transplant.**]**

Task 5 - Ensure an Orderly Transition of the NHLBI CBB to a Successful Contractor

In the event that this contract is terminated by the government, or upon contract expiration, the incumbent shall assist in ensuring an orderly and safe transition of the remaining COBLT CBB to a new location.

d. Reference Materials

Full details of the procedures can be found in the COBLT CBB Standard Operating Procedures at http://www.emmes.com.

e. Personnel

CBB personnel must include staff with documented specific training in stem cell processing and working with cryopreserved blood samples. Personnel must also have experience in maintaining federal and non-federal regulatory documents and using computer inventory systems.

[Note to Offerors: The experience, qualifications, competence, and availability of the investigative team should be clearly defined in your proposal.**]**

f. Special Requirements

It is anticipated that the following will become an advance understanding in the contract. All government furnished property will remain the property of the US government. All CBUs will remain the property of the US government until a CBU is removed from the CBB inventory and shipped to a transplant center for a potential transplant recipient at which time the CBU becomes the property of the contractor. All CBUs collected by the contractor as part of its cost-recovery program, will remain the property of the contractor.

C. REPORTS/ DELIVERABLES

REPORTING REQUIREMENTS

In addition to the reports required by federal and non-federal regulatory agencies, the preparation and submission of an annual Technical Progress Report to the NHLBI will be required in any contract resulting from this solicitation.

a. Annual Progress Report: This report shall include descriptive information on the transferred COBLT CBUs during the reporting period. The reporting period consists of the first twelve months of performance and will be due within 60 days of the contract anniversary and annually thereafter. The last annual report will be due on or before contract expiration. This report shall include the following summaries:

1. COBLT CBU use (transplant, quality assurance) since last report and overall;
2. data activities since last report (type of data collected, number of CBUs with data reported, publications);
3. maintenance, search, and shipping issues and corrective action taken;
4. current list of federal and non-federal governing groups and copy of FDA annual report, if applicable;
5. changes in CBB key personnel, facilities, governing bodies, and search registry use since last report;

DELIVERABLES

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

Item	Description	Quantity	Delivery Schedule
a.	Annual Progress Report	2	Annually during period of performance
b.	Government furnished property including CBU's and associated documentation		On or before contract expiration

D. EVALUATION FACTORS FOR AWARD WITH TECHNICAL EVALUATION CRITERIA

1. GENERAL

Proposals submitted in response to this solicitation will be reviewed by a technical evaluation group composed predominantly of federal workers convened by the DBDR Program Staff. Offerors may submit a proposal for only one (1) Cord Blood Bank.

Selection of an offeror for contract award will be based on an evaluation of technical proposals. Geographic location could become a factor in the government's selection of a contractor if successful offerors are located in the same general physical area. This would minimize the loss of both banks in the event of a catastrophic event such as an earthquake or flood, etc.

The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed technical evaluation criteria below. However, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

Past performance is not an evaluation criterion but it will be considered when determining contractor responsibility in accordance with FAR 9.104-3(b).

2. TECHNICAL EVALUATION CRITERIA

1. **Adequacy of managerial coordination and documented plans to list CBUs and provide outcome data.** **50%**

   Documented plans to coordinate the various aspects of a CBB program to safely store, retrieve, ship CBUs for transplant, and maintain CBUs and associated sample inventory. Documented plans and ability to ensure donor confidentiality is maintained, informed consent limitations are implemented, informed consent requirements are adhered to, and quality assurance CBUs, and associated samples, are used for validation purposes only. Documented plans and ability to comply with all safety guidelines and federal and non-federal regulations. Acceptability of plan to list CBUs on the National Bone Marrow Donor Registry and other search registries, if applicable. Ability to reserve and cancel CBU reservations for CBUs listed in multiple registries, if applicable. Ability to collect infusion and post-transplant outcome data, and submit data to a national registry. Acceptability of method for calculating CBU fee for non-licensed use.

2. **Adequacy and availability of facilities and resources.** **25%**

   Documented ability to provide facilities and resources to store COBLT CBUs, associated samples and source documentation for the contract period. Adequacy of the transition plan to relocate a Cord Blood Bank.

3. **Qualifications, experience, and availability of proposed personnel.** **25%**

   Ability to effectively manage and coordinate a cord blood bank. Documented experience and availability of a Principal Investigator with technical and administrative competence to operate a cord blood bank. Documented training, experience, and availability of administrative and laboratory personnel necessary to successfully perform the required work.

THE REMAINDER OF THIS RFP CONSISTS OF THE FOLLOWING SECTIONS:

II. Specific RFP Instructions and Provisions, and

III. Applicable RFP References

II. SPECIFIC RFP INSTRUCTIONS AND PROVISIONS

NOTICE TO OFFEROR: This section contains proposal instructions and information which are specifically related to this acquisition. The information provided below is only a portion of the instructions and notices required for the submission of a proposal. References to additional, more general, information and forms regarding proposal preparation are contained under Section III. Applicable RFP References.

The following specific RFP instructions and provisions apply to this Request For Proposal:

A. Proposal Intent Response Sheet
B. Government Notice for Handling Proposals
C. Packaging and Delivery of Proposal
D. NAICS Code and Small Business Size Standard
E. Number and Type of Award
F. Special Requirements
G. Reference Materials
H. Service of Protest
I. Technical Proposal Table of Contents
J. Other Provisions

A. PROPOSAL INTENT RESPONSE SHEET

RFP No. **NHLBI-HB-04-28**

TITLE OF RFP: **Maintenance of NHLBI Cord Blood Units**

FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY **April 7, 2004**. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

I INTEND TO SUBMIT A PROPOSAL

COMPANY/INSTITUTION NAME:

ADDRESS:

PROJECT DIRECTOR'S NAME:

TITLE:

TELEPHONE NUMBER:

RETURN TO:
Contracts Operations Branch
Attention: Lynda A. Bindseil
NIH, NHLBI
6701 ROCKLEDGE DR Rm 6134, MSC 7902
BETHESDA MD 20892-7902 or FAX TO: Ms. Lynda A. BIndseil (301) 480-3432

B. NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72.

(f) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(g) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

C. PACKAGING AND DELIVERY OF THE PROPOSAL

Shipment and marking shall be as follows:

EXTERNAL PACKAGE MARKING
In addition to the address cited below, mark each package as follows:

"RFP NO. NHLBI-HB-04-28
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

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

TECHNICAL PROPOSAL: ORIGINAL* AND Twelve (12) COPIES
BUSINESS PROPOSAL: ORIGINAL* AND Zero (0) COPIES

DELIVER PROPOSAL TO:

Contracts Operations Branch, Division of Extramural Affairs
National Institutes of Health
National Heart, Lung, and Blood Institute

Rockledge II, Room 6134
6701 ROCKLEDGE DR MSC 7902
BETHESDA MD 20892-7902

*THE ORIGINAL PROPOSAL MUST BE READILY ACCESSIBLE FOR DATE STAMPING.

D. SIC CODE AND SMALL BUSINESS SIZE STANDARD

NOTE: The following information is to be used by the offeror in preparing its Representations and Certifications, specifically in completing the provisions entitled, SMALL BUSINESS PROGRAM REPRESENTATIONS, FAR 52.219-1:

The North American Industry Classification System (NAICS) code for this acquisition is 621991.

THIS REQUIREMENT **IS NOT** SET-ASIDE FOR SMALL BUSINESS. However, the FAR requires in every solicitation (except for foreign acquisitions) the inclusion of the NAICS code and corresponding size standard which best describes the nature of the requirement in the solicitation.

E. NUMBER AND TYPE OF AWARD

It is anticipated that two (2) awards will be made from this solicitation and that awards will be made on or about September 1, 2004. The awards from this solicitation will be no-cost contracts with a fixed-price of $0 for term of ten years.

F. SPECIAL REQUIREMENTS

(1) Offerors should limit the size of their technical proposals to **50 double spaced pages of text**.

(2) It is anticipated that the following will become an advance understanding in the contract. All government furnished property will remain the property of the US government. All CBUs will remain the property of the US government until a CBU is removed from the CBB inventory and shipped to a transplant center for a potential transplant recipient at which time the CBU becomes the property of the contractor. All CBUs collected by the contractor as part of its cost-recovery program, will remain the property of the contractor.

(3) The contractor must provide details in the proposal on how newly collected CBUs will be distinguished and separated from the NHLBI CBU inventory.

G. REFERENCE MATERIALS

Full details of the COBLT CBB Standard Operating Procedures can be found at http://www.emmes.com

H. SERVICE OF PROTEST

In accordance with FAR 52.233-2 SERVICE OF PROTEST (NOV 1988):

(a) Protests, as defined in Section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General accounting Office (GAO) shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Ms. Lynda A. Bindseil
National Institutes of Health
National Heart, Lung, and Blood Institute
Contracts Operations Branch
6701 Rockledge Drive, Room 6134, MSC 7902
Bethesda, MD 20892-7902

The copy of any protest shall be received in the office designated above within one day of filing a protest with GAO.

I. TECHNICAL PROPOSAL TABLE OF CONTENTS

Please number each page of text. Type density and size must be 10-12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch.
The technical proposal should be organized as follows:

1. TECHNICAL PROPOSAL COVER SHEET (Form is located in the Streamlined RFP References under "FORMS, FORMATS, ATTACHMENTS") . . . . . .Page 1

2. TECHNICAL PROPOSAL TABLE OF CONTENTS . . . . . Page 2

3. ABSTRACT . . . . . Page 3
   State the proposal's broad, long-term objectives and specific aims. Briefly and concisely describe the research design and methods for achieving these goals. DO NOT EXCEED one page in providing the abstract. Identify the RFP Number, Institution and Principal Investigator on the abstract.

4. TECHNICAL PLAN (**LIMIT 50 double spaced pages of text (sections a.- d.)**. See Special Requirements above. Work samples submitted as part of the technical proposal are to be limited to 5 or fewer, and are to be provided in an appendix that is preceded by a table of contents. Refer to Technical Proposal Instructions located in the Standard RFP Instructions and Provisions under Streamlined RFP References for more detail.

   a. WORK STATEMENT
      1. Objectives.....Page #
      2. Approach.....Page #
      3. Methods.....Page #
      4. Schedule.....Page #

   b. PERSONNEL
   List of all Personnel in the project including Subcontractors, Consultants/Collaborators, by name, title, department and organization.....Page #

   PROVIDE NARRATIVE FOR:
   1. Principal Investigator/Project Director.....Page #
   2. Other Investigators.....Page #
   3. Professional Personnel.....Page #
   4. Support Staff.....Page #

   [NOTE: For all personnel except support staff, include a two-page biosketch under APPENDICES below.]

   c. FACILITIES, EQUIPMENT AND OTHER RESOURCES.....Page #
   List/describe all facilities, equipment and other resources available for this project.

   d. OTHER CONSIDERATIONS.....Page #
   (Use specifically titled subparagraphs, as applicable.)

5. OTHER SUPPORT.....Page #
   Complete the Form "Summary of Current and Proposed Activities." All key personnel must be listed on this form. The form is located in the Streamlined RFP References under "FORMS, FORMATS, & ATTACHMENTS."

6. TECHNICAL PROPOSAL COST INFORMATION.....Page #
   (Form located in the Streamlined RFP References under "FORMS, FORMATS, & ATTACHMENTS.")

7. LITERATURE CITED.....Page #

8. APPENDICES.....Page #
   List each Appendix and identify the number of pages for each one. Appendices must be clear and legible, and easily located. Include biosketches here.

J. OTHER INFORMATION

1. Attachment 1 - Equipment at Duke University Medical Center (DUMC)
2. Attachment 2 - Equipment at the University of California, Los Angeles (UCLA)
2. Attachment 3 - Preliminary list of FAR and HSSAR clauses to be included in any resultant contract

III. APPLICABLE RFP REFERENCES

This section identifies the items located in the Streamlined RFP References that are applicable to this Request For Proposal (RFP).

The entire file entitled "STANDARD RFP INSTRUCTIONS AND PROVISIONS" is applicable to this RFP, except as modified by the inclusion of items from the "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS" below.

The following items are applicable from the file entitled "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS". The full text of the provisions is available in the file.

List of optional provisions which apply to this specific RFP:

A. Notice: This requirement is Not Set-Aside for Small Business

The following items are applicable to this specific RFP and are located in the file entitled “FORMS, FORMATS, AND ATTACHMENTS”, under Streamlined RFP References:

SUBMIT WITH TECHNICAL PROPOSAL (with original and every copy of technical proposal)

1. Technical Proposal Cover Sheet
2. Summary of Current and Proposed Activities

SUBMIT WITH BUSINESS PROPOSAL:

1. Proposal Summary and Data record, NIH-2043.
2. Representations and Certifications, only one completed and signed original.

The “SAMPLE CONTRACT FORMAT-GENERAL” under the Streamlined RFP References is applicable to this RFP. Selected clauses, applicable to this acquisition, will be included in the contract.

Attachment 1 Equipment at Duke University*

Quantity	Item
1	ThermoGenesis N2 Bioarchive System (Includes 2,800 canisters, 2 centrifuge cups, 1 cord blood collection stand, 1 expressor & scale, and 1 tube sealer)
1	Advanced Quarantine System Vacume Chamber/ Accessories - ThermoGenesis
1	Sterile Tubing Welder - Terumo
1	Advanced Quarantine System Vacume Chamber/ Accessories - ThermoGenesis
1	Sterile Tubing Welder - Terumo
1	Forma Model 8523 Upright Freezer & Racks
1	ThermoGenesis N2 Bioarchive System (Includes 3,600 canisters)
1	Forma Scientific -86 degree Upright Freezer #8517
1	Inventory system #820018
1	Chart Recorder #2011310
1	Harris DLT-21V-85, -85C Upright Freezer
1	Inventory racks (for 2" dividers)
1	Boxes (2 dividers)
1	XLC 1211 Liquid Nitrogen Freezer & inventory system
1	Harris DLT-25V-85 Freezer with Inventory System
1	Centrifuge RC-3BP

***Additional equipment may be available but is not listed here.**

Attachment 2 Equipment at UCLA*

Quantity	Item
2	SCD 312 Sterile Tubing Welder
1	RC-3C PLUS Refrigerated Centrifuge w/accessories
1	XLC1841 Liquid Nitrogen Freezer (Long Term)
1	XLC511 Liquid Nitrogen Storage Container (for quarantine purposes)
1	Automated Cell Counter Coulter MDII, 8 with Graphics Printer
1	Sanyo Model MDP-U70V
1	XLC1211 Liquid Nitrogen Freezer and Inventory System
1	UltraLow Freezer -86C with inventory system
1	-20◦C Freezer (Harris IUF-30501)
1	Liquid Nitrogen Freezer (XLC 1841HE w/Inventory)
1	Liquid Nitrogen Freezer (XLC 810HE w/Inventory)

***Additional equipment may be available but is not listed here.**

Attachment 3

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED PRICE SERVICE CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates one or more clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Dec 2001	Definitions
52.204-7	Oct 2003	Central Contractor Registration
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-19	Oct 1997	Notification of Ownership Changes
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.224-1	Apr 1984	Privacy Act Notification
52.224-2	Apr 1984	Privacy Act
52.227-1	Jul 1995	Authorization and Consent
52.227-3	Apr 1984	Patent Indemnity
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.245-2	Jun 2003	Government Property (Fixed-Price Contracts)
52.249-4	Apr 1984	Termination for Convenience of the Government (Services) (Short Form)
52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)

Attachment 3

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED FIXED PRICE SERVICE CONTRACT - Rev. 01/2004].

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

FAR Clause 52.249-4, TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (SERVICES) (SHORT FORM) (APRIL 1984), is deleted in its entirety and FAR 52.249-2, TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (FIXED PRICE) (SEPTEMBER 1996) is substituted therefor.

NIH Request for Proposals (RFP) Directory

STREAMLINED RFP REFERENCES
STANDARD RFP INSTRUCTIONS AND PROVISIONS

Last updated on 09/29/2003

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1.

    1. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

1. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

1. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

1. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

Instructions to Offerors

1. **GENERAL INSTRUCTIONS**

Introduction

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions. Also, please note that the technical proposal must be organized and presented in accordance with the "Technical Proposal Table of Contents" found in the "Specific RFP Instructions and Provisions" section/attachment of an RFP.

Note: It is required that all Information Technology related procurements be Year 2000 compliant. For information regarding NIH policy on this click HERE.

1. **Contract Clauses**
2. Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.
3. **Authorized Official and Submission of Proposal**
4. The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the item entitled "Packaging and Delivery of Proposal" found in the "Specific RFP Instructions and Provisions" section/attachment of an RFP. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:
5.
    1. TECHNICAL PROPOSAL COVER SHEET
    2. Include RFP number, title, name of organization, name of Principal Investigator, names of other offeror key personnel, name of any subcontractor(s) and their proposed Principal Investigator(s), names of any collaborators or consultants, and indicate whether the proposal is an original or a copy.
    3. TECHNICAL PROPOSAL
    4. Format and organization of the technical proposal must follow the Table of Contents identified in the RFP, and must include the information requested in the Technical Proposal Instructions (below) and as otherwise specified in the RFP and REFERENCES. **All pages of the technical proposal must be numbered sequentially and these numbers must be consistent with the information outlined in**

the technical proposal table of contents.

5.
6. BUSINESS PROPOSAL
7. It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions (below) and as otherwise specified in the RFP and REFERENCES.

6. **Proposal Summary and Data Record (NIH-2043)**
7. The Offeror must submit with the business proposal a completed Form NIH-2043 (PDF version), with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. *(Note: A MS Word version of the NIH-2043 form may be accessed under the FORMS, FORMATS, AND ATTACHMENTS section of this website.)*
8. **Separation of Technical and Business Proposals**
9. The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See FORMS, FORMATS AND ATTACHMENTS, for format entitled TECHNICAL PROPOSAL COST INFORMATION). However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.
10. **Alternate Proposals**
11. You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.
12. **Confidentiality of Proposal -- HHSAR 352.215-12, Restriction on Disclosure and Use of Data**
13. The proposal submitted in response to this request for proposals may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend.
14. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act:
    1.
    2. Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) Officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
    3. The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act, and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

4. If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal; the Government shall have the right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
5. The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.
6. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)
7. In addition, the offeror should mark each page of data it wishes to restrict with the following legend:
    1.
    2. "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal."
    3. NOTE: Offerors are cautioned that proposals submitted with the restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

15. **Evaluation of Proposal**
16. The Government will evaluate technical proposals in accordance with the criteria set forth in the Technical Evaluation Criteria of each specific Streamlined Technical RFP. Cost and past performance will be addressed in each specific RFP, either as specific Technical Evaluation Criteria or by indicating what their relative importance and roles are. If past performance is not addressed, then it has been determined by the Contracting Officer that past performance does not apply to this R & D solicitation as a separate evaluation factor.
17. **Use of the Metric System of Measurement**
18. It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.
19. The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:
20.
    1. Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).
    2. Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.
    3. Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.
21. **Privacy Act**
22. The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.
23. The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and, as applicable, P.L. 92-218 or 95-83, as amended.
24. Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.
25. Failure to provide any or all of the requested information may result in a less than adequate review.
26. In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.
27. Provision of the social security number is voluntary. Social security numbers are requested for the purpose of

accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

28. The information provided by you may be routinely disclosed for the following purposes:
    1. to the cognizant audit agency and the General Accounting Office for auditing.
    2. to the Department of Justice as required for litigation.
    3. to respond to congressional inquiries.
    4. to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.
29. **Selection of Offeror**
    1. The acceptability of the scientific and technical portion of your research contract proposal will be evaluated by a technical review committee. They will evaluate your proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
    2. The business portion of each contract proposal will be subjected to a cost analysis.
    3. Best Value Analysis. Although technical is paramount on this R & D acquisition, a final best-value analysis may be performed, taking into consideration the results of the technical evaluation, cost and past performance analyses, and ability to complete the work within the Government's required schedule, as appropriate. The Government reserves the right to make an award to the best advantage of the Government, all factors considered.
    4. The Government reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet Government requirements. Synopses of awards exceeding $25,000 and offering subcontracting opportunities will be published in the Commerce Business Daily.

1. **Small, Small Disadvantaged, HUBZone and Women-Owned Small Business Subcontracting Plan**
2. If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small, Small Disadvantaged, HUBzone and Women-Owned Small Business Model Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation.
3. a. **THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.**
4. b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
5. c. The offeror understands that:
6.
    1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
    2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.
    3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.
6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned and HUBZone small business concerns as subcontractors.
2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, and HUBZone Small Businesses.
3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned and/or HUBZone small business concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned and HUBZone small business concerns.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that small, small disadvantaged and women-owned small business concerns have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small, Small Disadvantaged, Women-Owned and HUBZone Small business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned and HUBZone small business concerns and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan. A Sample Subcontracting Plan is contained in the FORMS, FORMATS AND ATTACHMENTS section of this website. Please refer to the instructions in your RFP to determine when (and if) submission of this plan is required.

1. **Salary Rate Limitation Information for Offerors**
2. Offerors are advised that pursuant to Public Law 106-113, no NIH funds may be used to pay the direct salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of **$136,700** as

specified in the Public Law setting forth such limitations. The applicable Public Law number, the fiscal year to which it applies, and the dollar amount of the salary rate limitation may be obtained from the Contracting Officer identified in each specific RFP, if this information is not included in a specific RFP.

3. Direct salary is considered to be exclusive of Overhead, Fringe Benefits and General and Administrative expenses. This does not preclude the offeror from absorbing that portion of an employee's salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds the rate specified. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's salary exceeds any salary rate ceiling established in future appropriations acts. The applicable salary rate limit also applies to individuals proposed under subcontracts.
4. **Institutional Responsibility Regarding Conflicting Interests of Investigators**
5. EACH INSTITUTION MUST:
6.
    1. Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
    2. Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
    3. Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
    4. Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
    5. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
    6. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
    7. Certify, in each application/proposal for funding to which the regulations applies, that:
    8.
        1. there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
        2. prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
        3. the Institution agrees to make information available, upon request, to the awarding

component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
4. the Institution will otherwise comply with the regulations.

7. **Institutional Management of Conflicting Interests**
8.
    1. The designated official(s) must: (i) review all financial disclosures; and (ii) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.
    2. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:
        1. public disclosure of significant financial interests;
        2. monitoring of research by independent reviewers;
        3. modification of the research plan;
        4. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
        5. divestiture of significant financial interests; or
        6. severance of relationships that create actual or potential conflicts of interests.

    3. An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.
9. **ROTC Access and Federal Military Recruiting on Campus**
10. Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.
11. Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (i) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (ii) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.
12. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**
13. This Solicitation incorporates the following solicitation provisions by reference with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.
14. FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):
    1. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
    2. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
    3. Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data, 52.215-20 (October 1997)
    4. Order of Precedence, 52.215-33 (October 1997)
    5. Preaward On-Site Equal Opportunity Compliance Review (over $10,000,000), 52.222-24 (Feb 1999)

15. **Small Disadvantaged Business Participation Plan**
16. In accordance with FAR part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract shall be evaluated in unrestricted acquisitions expected to exceed a

total estimated cost of $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.201 and 19.1202). If an SDB concern waives the price evaluation adjustment (PEA) at Subpart 19.11, participation in performance of that contract includes the work expected to be performed by the SDB concern at the prime contract level.

17.
    1. **Offerors shall submit the following information in one clearly marked section of their business proposal.**
    2. A plan on the extent of participation of Small Disadvantaged Business concerns in performance of the contract. Participation in performance of the contract includes the work expected to be performed by SDB concern(s). This can include SDB (as prime contractor), joint ventures, teaming arrangements, and subcontracts. Include the following information in SDB participation plans:
    3.
        1. The extent of an offerors commitment to use SDB concerns. Commitment should be as specific as possible, i.e. are subcontract arrangements already in place, letters of commitment, ect. Enforceable commitments will be weighted more heavily than non enforceable ones.
        2. Specifically identify the SDB concerns with point of contact and phone number.
        3. The complexity and variety of the work SDB concerns are to perform.
        4. Realism for the use of SDB in the proposal.
        5. Past performance of the Offerors in complying with subcontracting plans for SDB concerns
        6. Targets expressed as dollars and percentage of total contract value for each participating SDB; which will be incorporated into and become part of any resulting contract.
        7. The extent of participation of SDB concerns in terms of the value of the total acquisition.

    4. SDB Participation information will be used for both responsibility determinations and as an evaluation factor against which offeror's relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates realistic commitments to use SDB concerns relative to the size and complexity of the acquisition under consideration. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's commitment to SDB participation.
18. **HUBZone Small Business Concerns**
19. Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

1. **TECHNICAL PROPOSAL INSTRUCTIONS**

Introduction

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken, and must include information on how the project is to be organized, staffed, and managed.

The Technical Proposal should be organized and presented according to the **"Technical Proposal Table of Contents"** found in the "Specific RFP Instructions and Provisions" section/attachment of the RFP. All pages of your technical proposal must be numbered sequentially and these numbers must be consistent with the information outlined in the technical proposal table of contents.

1. **Technical Proposal**
2. The technical proposal should respond to the items set forth below:
3.
    1. Personnel
    2. Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.
    3. OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.
    4.
        1. Principal Investigator/Project Director
        2. List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible. If the Principal Investigator proposed for this RFP is committed in excess of 100% of his/her time the proposal must include appropriate explanations.
        3. Other Investigators
        4. List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.
        5. Additional Personnel
        6. List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:
            1. The specific items or expertise they will provide.
            2. Their availability to the project and the amount of time anticipated.
            3. Willingness to act as a consultant.
            4. How rights to publications and patents will be handled.
        7. Resumes
        8. Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. Resumes must not exceed two pages.

5. Statement of Work
6.
    1. Objectives
    2. State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.
    3. Approach
    4. Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.
    5. Methods
    6. Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.
    7. Schedule
    8. Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

7. Facilities and Resources
8. List/describe all facilities and resources available for this project, including any equipment.
9. Other Considerations
10. Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:
    1. Any agreements and/or agrrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
    2. Unique arrangements which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
    3. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
    4. Other factors you feel are important and support your proposed research.
    5. Recommendations for changing reporting requirements or other deliverables if such changes would be more compatible with the offeror's proposed schedules.

11. Summary of Related Activities
12. The offeror shall complete and include with the technical proposal the "Summary of Current and Proposed Activities" form found in, FORMS, FORMATS, AND ATTACHMENTS. Include this form (or similar formatted document) with the Other Support portion of your technical proposal.
13. Technical Proposal Cost Information
14. Complete and include with your Technical Proposal the "Technical Proposal Cost Information"

format contained in FORMS, FORMATS, AND ATTACHMENTS.

15. Technical Evaluation
16. Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as set forth in the Technical Evaluation Criteria of each specific Streamlined Technical RFP.
17. Additional Technical Proposal Information
18.
    1. Proposals which merely offer to conduct a program in accordance with the requirements of the Governments's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the projects objectives.
    2. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon information contained in the offeror's proposal only.

1. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**
2. The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.
3. **Cost and Pricing Data**
4.
    1. General Instructions

(1) You must provide the following information on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of offeror;
3. Name and telephone number of point of contact;
4. Name of contract administration office (if available);
5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
6. Proposed cost; profit or fee; and total;
7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s)

the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

10. Date of submission; and
11. Name, title and signature of authorized representative.

(2) In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

(3) As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
2. The nature and amount of any contingencies included in the proposed price.

(4) You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

(5) When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

(6) Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

(7) If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

(8) As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

1. **Cost Elements**
2. Depending on your system, you must provide breakdowns for the following basic costelements, as applicable:
3.
    1. Direct Labor.
    2. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish basis for estimates.
    3. Fringe Benefits.
    4. Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or organizational guidelines.
    5. Materials and services.

6. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph (2), below. These requirements also apply to all subcontractors if required to submit cost or pricing data.
    1.
    2. (a) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).
    3. (b) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 ($500,000) and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide aseparate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.
7. Indirect Costs.
8. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.
9. Special Equipment.
10. If direct charge, list any equipment proposed including description, price, quantity, total

price, purchase of lease, and the basis for pricing.

11. Travel.
12. Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.
13. Other Costs.
14. List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.
15. Royalties.
16. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:
    1. Name and address of licensor.
    2. Date of license agreement.
    3. Patent numbers.
    4. Patent application serial numbers, or other basis on which the royalty is payable.
    5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
    6. Percentage or dollar rate of royalty per unit.
    7. Unit price of contract item.
    8. Number of units.
    9. Total dollar amount of royalties.
    10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).
17. Facilities Capital Cost of Money (Commercial Organizations, only).
18. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

4. **Formats for Submission of Line Item Summaries.**
5. The detailed breakdown shall be in a format similar to that shown on the "Business Proposal Cost Information" form found under the "FORMS, FORMATS, AND ATTACHMENTS" section of the NIH RFP Directory. For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.
6. Further, in an effort to assist the cost proposal review process, Offerors who have prepared their business proposal using the following software spreadsheet programs are requested to provide a copy of the cost proposal spreadsheet(s) on a computer disk (high density) along with the submission of your paper copies of the business proposal. IBM PC compatible software programs are: Excel; Lotus 1-2-3; and Quattro Pro. If you would like to use a pre-formatted cost proposal spreadsheet click here (also available under "Business Proposal Cost Information). [Note: This is an EXCEL spreadsheet.]
7. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
8. By submitting your proposal, you grant the Contracting Officer or an authorized representative the

right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

[Note to Offeror: For RFPs which are using "JUST IN TIME" procedures, the data substantiating the costs or prices proposed (i.e., payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.]

1. **Qualifications of the Offeror**
2. *[Note to Offeror: The Evaluation Factors for Award portion of the Streamlined Technical RFP will specify how past performance is to be treated. If past performance is a specific, weighted evaluation factor, then "Qualifications of the Offeror" does not apply. In that case, the RFP would reference the "Past Performance Information" section of the "Optional RFP Instructions and Provisions."]*
3. You are required to submit a summary of your General Experience, Organizational Experience Related to this RFP, Performance History, and Pertinent Contracts and Grants.
4.
    1. General Experience
    2. General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.
    3. Organizational Experience Related to the RFP
    4. Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP (the evaluation of proposed personnel will be done through the applicable technical evaluation criterion).
    5. Performance History
    6. Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which are comparable or related to the effort required by this RFP.
    7. Pertinent Contracts
    8. Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. List contracts awarded by the Government that involved similar or related work to that called for in this RFP. Include the contract number, contracting agency, contract dollar value, dates contract began and ended (or ends), description of contract work, explanation of relevance of work to this RFP, names and telephone numbers of the Contract Specialist and the Health Science Administrator.
    9. Pertinent Grants
    10. Pertinent grants is defined as a listing of each related grant completed within the last three years or currently in process. List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names and telephone numbers of the Grant Specialist and the Health Science Administrator, identification of the work, and when performed.
    11. You are cautioned that omission of the above information or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are relevant to the ability of the offerors to perform and, while not a specific, weighted evaluation factor they are inherent in one or more technical evaluation criterion. Also, they may be used to conduct a relative assessment of offerors during the source selection process if the Evaluation Factors for Award in the specific RFP so indicates.

5. **Property, Equipment, Facilities**
6.
    1. It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes, in addition to the description and estimated cost of each item:

        1. An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
        2. No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

    2. The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

    3. If an offeror intends to use existing Government-owned facilities in the performance of this proposed contract, the following shall be furnished with the offer: (1) Description and value of all Government production and research property which the offeror or his/her anticipated subcontractors propose to use on a rent-free basis and the cognizant Government Contract Number; (2) Written permission of the Contracting Officer having cognizance of the property for use of that property without charges; (3) Amount of use (in months) to be made of such property, and (4) Amount of rent which would otherwise be charged for such use, computed in accordance with applicable procurement regulations.

    4. The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

7. **Royalties**
8. The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.
9. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**
10. The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.
11.
    1. (1) The solicitation number (or other procurement identification number). (2) The offeror's name and remittance address, as stated in the offer. (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information. (4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent. (5) The offeror's account number and the type of account (checking, savings, or lockbox). (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent. (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit

Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

12. **Financial Capacity**
13. The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.
14. **Incremental Funding** --(Note: This is applicable if the RFP has stated that the contract resulting from this solicitation will be incrementally funded.)
15. An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:
16. Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
17. **Subcontractors**
18. If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

    1. Willingness to perform as a subcontractor for specific duties (list duties).
    2. What priority the work will be given and how it will relate to other work.
    3. The amount of time and facilities available to this project.
    4. Information on their cognizant field audit offices.
    5. How rights to publications and patents are to be handled.
    6. A complete cost proposal in the same format as the offeror's cost proposal.

19. **Representations and Certifications**
20. One copy of the Representations and Certifications (link to RFP REFERENCES) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.
21. Travel Policy and Annual Report
22. The Proposer's Travel Policy and Annual Report are two items that will be requested of offerors in the competitive range, offerors who submit FRPs, or offerors who will receive an award (i.e., "Just in Time"), rather than of all offerors with their initial business proposals. *(Note: In cases where the RFPs specifically state that awards may be made without discussions, offerors must submit these documents with their initial business proposal.)*

NOTE: If additional "Just in Time" items are selected from the Optional Instructions and Provisions, then the RFP will so indicate. If you would like to use a pre-formatted cost proposal spreadsheet click here (also available under "Business Proposal Cost Information). Note: This is an EXCEL spreadsheet.

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This page was last updated on September 29, 2003.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
PROPOSAL SUMMARY AND DATA RECORD

RFP NUMBER/CONTRACT NUMBER

PROJECT TITLE (Title of RFP or Contract Proposal)

LEGAL NAME AND ADDRESS OF OFFEROR

PLACE OF PERFORMANCE (Full address including ZIP)

TYPE OF CONTRACT PROPOSED
☐ COST-REIMBURSEMENT ☐ FIXED PRICE ☐ COST-PLUS-FIXED-FEE ☐ OTHER

ESTIMATED TIME REQUIRED TO COMPLETE PROJECT

PROPOSED STARTING DATE

ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From budget)

DOES THIS PROPOSAL INCLUDE A SUBCONTRACT ☐ YES ☐ NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)

NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL. NO.
NAME AND TITLE OF CO-INVESTIGATORS (Use attachment if necessary)	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL. NO.

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS — AREA CODE/TELEPHONE NUMBER

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS — AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS? ☐ YES ☐ NO

Institution's General Assurance re Human Subjects — DATE APPROVED — ☐ PENDING
Institution's Review Board's approval of this proposal — DATE APPROVED — ☐ PENDING
An example of the informed consent for this study is enclosed ☐ YES ☐ NO
A Clinical Protocol is enclosed ☐ YES ☐ NO

OFFEROR'S ACKNOWLEDGEMENT OF AMENDMENTS TO THE RFP (Use attachment if necessary)

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY

NUMBER OF EMPLOYEES CURRENTLY EMPLOYED

DOLLAR VOLUME OF BUSINESS PER ANNUM

THIS OFFER EXPIRES DAYS FROM THE DATE OF THIS OFFER. (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
EMPLOYER IDENTIFICATION NUMBER	DATE OF OFFER

NIH 2043 (Rev. 6/82)

Provision of the Social Security Number is voluntary. Social Security Numbers are requested for the purpose of accurate and efficient identification, review, and management of NIH Extramural Programs. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

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