



Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMP WEBSITE <http://www.niaid.nih.gov/contract/default.htm> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended. NOTE: The issuance of this solicitation does not commit the government to an award.			
RFP Number: NIH-NIAID-DAIDS-04-04	Just In Time: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Small Bus. Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS Code: 54171 Size Standard: 500 Employees	Level of Effort: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Total Effort: []
TITLE: Microbicide Design and Development Teams			
Issue Date: March 19, 2004	Due Date: August 13, 2004 Time: 4:00 PM, EST	Technical Proposal Page Limits: <input type="checkbox"/> Yes (see "How to Prepare and Submit Electronic Proposals") <input checked="" type="checkbox"/> No	
ISSUED BY: Lawrence M. Butler Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612		<input checked="" type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>	
		NO. OF AWARDS: <input type="checkbox"/> Only 1 Award <input checked="" type="checkbox"/> Multiple Awards	PERIOD OF PERFORMANCE: 5 years beginning on or about 05/16/2005
Offers will be valid for 365 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)			
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of 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 HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.			
POINT OF CONTACT -- Donald E. Collie --COLLECT CALLS WILL NOT BE ACCEPTED--			
Telephone: Direct 301-496-0992 Main 301-496-0612		Fax 301-402-0972	E-Mail DCollie@niaid.nih.gov

TABLE OF CONTENTS

SECTION A -- SOLICITATION/CONTRACT FORM COVER PAGE

BACKGROUND

STATEMENT OF WORK (with attachments)

NOTES TO OFFERORS

REPORTING REQUIREMENTS and OTHER DELIVERABLES

SECTIONS B – H -- UNIFORM CONTRACT FORMAT - GENERAL

SECTION I -- GENERAL CLAUSES and ADDITIONAL CLAUSES / SUBSTITUTED CLAUSES

SECTION J -- LIST OF ATTACHMENTS

SECTION K -- REPRESENTATIONS AND CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR QUOTERS (NEGOTIATED)

SECTION L -- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. General Information
2. Instructions to Offerors
 - a. General Instructions
 - b. Technical Proposal Instructions
 - c. Business Proposal Instructions

SECTION M -- EVALUATION FACTORS FOR AWARD

Background

HIV Microbicide Design and Development Teams

DAIDS-04-04

With current global estimates exceeding 40 million people infected with HIV and the majority of these infections acquired through sexual intercourse, there is an intensified need for the development of safe, effective, topically applied pharmacologic barriers to prevent sexually transmitted HIV infection. Results from Phase III efficacy trials of vaginal products containing the spermicidal detergent, nonoxynol-9 (N-9), have indicated that N-9 does not provide protection against the sexual transmission of HIV. Until recently no other microbicide candidates have been sufficiently advanced to be considered for Phase III testing. Those candidates now poised for efficacy trials are predominantly representatives of the same class of compounds that block HIV attachment with the exception of one direct virucidal agent that acts via acidification of the mucosal environment. Promising candidates with other modes of action and/or more encouraging safety profiles languish in the absence of sufficient corporate investment in clinical development. This applies to products with considerable potential for development as topical microbicides that are the focus of active commercial development only as therapeutic agents, and products that have been abandoned as therapeutic agents for HIV/AIDS without exploiting the investment already made by evaluating the agent as a microbicide.

The discovery, development, and evaluation of promising HIV microbicides is a high priority for the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH). To augment the microbicide product pipeline, we are seeking opportunities to advance microbicide concepts toward the product stage via a focused, product development-based approach. Specifically, the long-range goal of this solicitation is the development of new safe and effective microbicide candidates that merit further evaluation in large human trials. The HIV Microbicide Design and Development Teams (HMDDT) solicitation seeks to fund consortia of scientists with product development experience from industry and/or academia that have 1) identified a promising microbicide concept, and 2) devised a plan for its targeted development into a product testable in humans. A microbicide product is defined here to be a material and its manner of administration that could reasonably provide protection against the sexual transmission of HIV safely, even when used repeatedly. The expectation is that the Teams advance their microbicide concepts along a well-defined development path in a timely manner to a microbicide product and into clinical testing within the five-year period of the award. Offerors are encouraged, but not required to conduct phase I/II trials in collaboration with the NIH/NIAID/DAIDS-supported HIV Prevention Trials Network (the HPTN; <http://www.hptn.org>). Support for Phase III studies will not be funded under this solicitation.

Because the goal of this effort is the development of microbicide products, each Team will be required to demonstrate proven scientific and development expertise, and provide a comprehensive plan that lays out clearly defined objectives and milestones for the project's duration. Because the design and development path for any microbicide product cannot be entirely anticipated, the Team must articulate its vision of how new scientific findings will be integrated into the proposed goals and milestones. Offerors will be required to articulate and implement a strategic research plan that includes: (a) key development objectives and a detailed work plan describing proposed time schedules for achieving contract objectives and milestones, and maintaining quality control over the implementation and operation of the contract, (b) how decisions to proceed or not proceed will be made (i.e. specific qualitative and quantitative criteria for product advancement through each stage of preclinical, including IND-enabling, development and Phase I/II safety evaluations), (c) plans for GMP microbicide lot production and packaging, and (d) obtaining the necessary regulatory and human subjects approvals to proceed. This strategic plan shall articulate how the Team will efficiently allocate and utilize the resources, and redirect the focus (including reallocation of funds) depending upon the project's changing needs and emerging new knowledge. It shall, also, articulate how patent coverage and licensing of the resulting HIV microbicide will be obtained and the procedures to be followed for the resolution of potential legal issues that may arise.

**Statement of Work
HIV Microbicide Design and Development Teams
RFP DAIDS-04-04**

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

Specifically, the Contractor shall:

1. Identify a specific microbicide concept to be pursued in a well planned and managed, comprehensive, multidisciplinary, targeted development effort culminating in the production and clinical testing of a promising HIV microbicide candidate or candidates **(See Note to Offeror #1-3)**.
2. A Strategic Research Plan **(See Note to Offeror #4-6)**:

The contractor shall submit and shall implement the Strategic Research Plan. The strategic plan shall articulate how the Team will efficiently allocate and utilize the resources, redirect the focus (including reallocation of funds) depending upon the project's changing needs and emerging new knowledge, obtain patent coverage and licensing of the resulting HIV microbicide, and what procedures will be followed for the resolution of potential legal issues that may arise. This plan shall be approved by the Project Officer as updated bi-annually. The plan shall also include the following:

- a. key development objectives and a detailed work plan describing proposed time schedules for achieving Contract objectives and milestones, and maintaining quality control over the implementation and operation of the Contract
 - b. a plan delineating how decisions to proceed or not proceed will be made (i.e. specific qualitative and quantitative criteria for advancement of a microbicide candidate(s) through each stage of preclinical, including IND-enabling, product development and Phase I safety evaluation)
 - c. plans for GMP microbicide lot production and packaging and for obtaining the necessary regulatory and human subjects approvals to proceed **(See Note to Offeror #7)**
 - d. Specific Microbicide Production Milestones. A set of milestones should be mapped out for each microbicide concept, if iterative design/formulation will result in multiple Phase I trials, and/or if separate Phase I trials are anticipated for each agent in a microbicide containing more than one active component (excluding formulation excipients). **(See Note to Offeror #9)**
3. Provide a research and administrative team that includes all expertise needed for the development, optimization, pre-clinical and clinical testing, and production of an HIV microbicide(s) based on the concept chosen by the Offeror **(See Note to Offeror #8)**.
 4. Provide infrastructure, facilities, and resources for performing all phases of this Contract, including production of an optimized microbicide(s) under GMP (Good Manufacturing Practices, as defined in the US Code of Federal Regulations – 21 CFR §211) conditions, GLP (Good Laboratory Practices – 21 CFR §58) performance of IND-enabling preclinical animal studies, and GCP (Good Clinical Practices – 21 CFR §312 and ICH Guidelines document E6) performance of clinical studies in humans if clinical studies will be performed by the Offeror, on its own, rather than through the DAIDS HIV Prevention Trials Network.
 5. Report progress according to Reporting Requirements (refer to the “Deliverables and Reporting Requirements” in this Contract).

6. Meet with the Project Officer and the External Steering Committee associated with this Contract. **(See Note to Offeror #9).**
 - a. The Contractor and the NIH, after Contract award, shall jointly establish an External Steering Committee for the Contract. The Contractor's key personnel shall meet with the Project Officer and the Team's External Steering Committee at periodic intervals to be scheduled after Contract award to review progress and anticipated or existing problems.
 - b. In the middle (6 month mark) of each Contract year, the Contractor shall host a site visit for NIAID Contract and Program staff, and their External Steering Committee. The Contractor's Principal Investigator and all co-investigators shall attend this meeting. The co-investigator and/or other pertinent staff shall present an update and summary of results generated on each sub-project. These presentations shall include summaries of all goals or milestones reached during the review period and a description of all problems encountered that will impact on the achievement of particular goals and milestones as outlined in the Contractor's research plan. The Principal Investigator, co-investigator and staff representing each project and subproject shall describe goals and milestones and development objectives for the coming year. Additionally, application of the policies and procedures for monitoring the direction of specific projects shall be presented. For Contractors with foreign subcontracts, this annual site visit also will report details about approvals for manufacturing or testing that have been obtained from both the U.S. and foreign governments.

Notes To Offerors

HIV Microbicide Design and Development Teams

DAIDS-04-04

NOTE 1 TO OFFEROR: For purposes of this solicitation a microbicide concept includes (1) both active component(s) and formulation that, when applied topically to cervicovaginal and/or anorectal mucosa, safely protects against the transmission of HIV, and (2) the method of delivery. Examples of active components include, but are not limited to, proteins, small molecules, natural products, agents controlling pH, metal and chelating agents, glycans, surfactants, polymers and bacterial and other live vectors. These active components may be formulated in a number of ways, including creams, gels, and suppositories. The delivery of the formulated active component(s) can be accomplished by applicators, devices such as vaginal rings, or other methods. In these examples the active component(s) and formulation are part of the microbicide concept, while the applicators or rings are the method of delivery. It is expected that the Offeror will propose to optimize the safety and efficacy of the active component(s) and formulation of the candidate microbicide concepts as well as the chosen delivery system(s).

This solicitation seeks proposals to support development of microbicide concepts and the chosen delivery systems that include mechanisms of action that target one or preferably more than one viral and/or cellular processes involved in sexual transmission of HIV. Concepts based on surfactants or sulfated polymers must represent significant novelty e.g., higher potency, and/or increased safety, compared to products that have been or are currently being evaluated in clinical trials.

NOTE 2 TO OFFEROR: The Offeror shall provide in their proposal adequate justification to warrant the extensive effort of optimization, production and testing of the microbicide concept(s) chosen for development. This justification shall include the rationale for the selection of specific active components, formulation and method of delivery. The Offeror shall also provide a scientific explanation for how the proposed concept will be developed into a product suitable for worldwide use.

As part of the justification of the choice of concept, the Offeror shall include relevant information from other previously tested candidate microbicides. For those concepts where there is a paucity of supporting *in vivo* or *in vitro* data, the Offeror shall provide other justification, such as positive data from the use of this concept in other types of vaginal or rectal products. In these cases, information that demonstrates similarities to those used for chronic long-term prevention will be of paramount importance.

NOTE 3 TO OFFEROR: The Government is aware that no single organization or institution may have the expertise and facilities required to perform all requirements set forth in this work statement. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. If a subcontractor(s) is proposed, similar technical information as that required of the prime Contractor; i.e., technical approach, knowledge, methods, experience, personnel qualifications, specific responsibilities and work to be performed for contract, facilities, resources, etc., shall be provided by the subcontractor(s) as part of the Technical Proposal. Since the Government is seeking to support the best possible design and development teams, the primary Contractor is not limited to a domestic institution or organization. In addition, subcontracting to foreign organizations /institutions is permitted. Cost details shall be provided for the subcontractor(s). The review and selection criteria for adding additional subcontractors during Contract performance shall be clearly delineated. Additionally, the relationship between the subcontractor(s) and the prime Contractor in conducting the work statement shall be clearly delineated.

NOTE 4 TO OFFEROR: International collaborations are encouraged under this solicitation. If international sites are proposed for clinical studies, the Offeror must show how the Team plans to obtain the necessary approvals from the foreign government(s) to conduct the studies. The Offeror shall include plans for how the Team will satisfy human research subject protection concerns, as expressed by the DHHS OHRP, in accordance with the norms and standards governing such studies performed using U.S. Government funds.

NOTE 5 TO OFFEROR: The Offeror shall provide a draft agreement signed by all parties involved outlining procedures to be used for: (1) obtaining patent coverage and licensing of the resulting HIV microbicide(s), and (2) procedures to be followed for the resolution of potential legal issues that may arise. **IF THIS AGREEMENT IS NOT INCLUDED IN THE OFFEROR'S PROPOSAL BY THE CLOSING DATE, THE PROPOSAL WILL NOT BE EVALUATED.** The Offeror should also plan to obtain patent coverage and/or licensing for all substances and technologies used in the microbicide product(s) made for research and clinical trials.

NOTE 6 TO OFFEROR: A detailed development plan that includes a conceptual framework, design (including selection of a microbicide concept), iterative evaluations, appropriateness and adequacy of the experimental approach and methodology proposed, and assays to detect inhibitory activity and evaluate potential toxicity, must be submitted as a part of the Technical Proposal. This plan must include proposed time schedules for achieving Contract objectives and milestones, criteria for advancement of microbicide candidate(s), and procedures for maintaining quality control over the implementation and operation of the Contract. As part of this plan, discuss how scientific evaluation of the concept will lead to a microbicide suitable for worldwide use.

As an element of iterative concept development and refinement, human clinical studies will be supported. The Offeror must include the decision criteria for determining when a microbicide concept is advanced enough to enter human studies. Collaboration with NIAID-supported prevention trials networks for the conduct of phase I/II studies is encouraged, but not required. If the Offeror chooses to collaborate with an NIAID-sponsored trial network to perform clinical trials with the proposed microbicide product(s), a "letter-of-intent" from the appropriate network should be submitted with the proposal. **Support for phase III studies will not be funded under this solicitation.**

The Technical Proposal will include Technical Proposal Cost Information (5 year). List development costs by activity per specific milestones proposed (e.g., see Generic Microbicide Production Milestones) This Cost Information 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. The technical proposal should disclose the Offeror's technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions. 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.

NOTE 7 TO OFFEROR: Offerors determined to be in the competitive range shall undergo a pre-award site visit with an emphasis on assessing their GMP, GLP, and QC/QA capabilities. The results of this pre-award site visit shall be a factor in final Source Selection for award of Contract. This will be evaluated under Section M, Evaluation Factors for Award, Element 4, Facilities and Resources, Items d) through f) as listed below:

- d) capacity to perform regulatory- and human subjects protection-compliant clinical trial(s), or a letter-of-interest from the appropriate NIAID-sponsored trial network in performing a clinical trial with the Offeror's proposed microbicide product(s). Capacity should be shown for the prime and all subcontractors.
- e) capacity to perform FDA-required safety, potency, and other pre-clinical studies
- f) capacity for production and packaging of the microbicide product under GMP/GLP conditions

Since vertebrate animals will be needed for preclinical studies to satisfy regulatory agency requirements and are likely to be used in other studies required for product development, the Offeror should address in the Technical Proposal, provisions for complying with NIH guidelines for the humane care and use of laboratory animals as delineated by the Office of Laboratory Animal Welfare (OLAW; <http://grants.nih.gov/grants/olaw/olaw.htm>). If clinical trials will be performed under the Contract, the Offeror should address in the Technical Proposal, issues of human subject protection (justification of potential benefits to subjects and/or society vs. risks to subjects, and adequacy of protection against risks including informed consent measures), provisions of data and safety monitoring (adequacy of monitoring approach and reporting procedures), and appropriateness of representation of women, minority subpopulations and children in clinical studies (including justification for any exclusions,

adequacy of plans for recruitment, outreach, analysis, and risks to participants). Copies of the Department of Health and Human Services (DHHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Office of the Secretary (OS), DHHS - (<http://ohrp.osophs.dhhs.gov/index.htm>). The NIH guidelines for inclusion of women and minorities, and for inclusion of children as subjects in clinical research are available at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm and at <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>, respectively.

NOTE 8 TO OFFEROR: A Team must include strong scientific leadership. The Team leadership must also possess significant experience in the management, design, and execution of large multi-faceted programs focused on product development and manufacture. However, these two roles need not be filled by a single individual.

In response to this RFP, the Offeror shall describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. In addition, the Offeror shall describe an administrative framework indicating clear lines of authority and responsibility for the project's management.

Documentation shall also be provided on the qualifications, knowledge, experience, education, competence, availability, and decision-making authority of the Principal Investigator, Project Manager, Technical Staff, and Administrative Support Staff. Offerors must provide information on the extent to which outside consultants will be used, as well as assurance of their availability, and the percentage of time each staff member (including proposed subcontractors and consultants) will contribute to the project.

NOTE 9 TO OFFEROR: The Contract will be subject to periodic review of performance and approval by an External Steering Committee as described under the "Reporting Requirements" section of this RFP. Each HIV Microbicide Design and Development Team will have an independent External Steering Committee. The membership of the External Steering Committee will be jointly proposed and agreed to by the Contractor and the NIH after the award is made; **do not propose members of the External Steering Committee at this time.** The NIH and the Contractor will convene the External Steering Committee, and the Contractor will pay the travel expenses of the Committee. (See Reporting Requirements.)

The progress of the HIV Microbicide Design and Development Team will be determined by the completion of their negotiated goals and milestones according to the negotiated schedule. The Government expects that a Team will identify no greater than 30-40 milestones for the full 5-year period of this project. Incremental funding and payment of fee will be provided on the basis of the Team achieving its stated goals and/or milestones. The size of each increment will be negotiated prior to award of the individual Contract. Offerors are encouraged to propose fees linked to accomplishment of key milestones. Offerors are also invited to propose additional incentive mechanisms in their proposal. There can be incentives for early accomplishment of milestones while fees may be reduced for delay in meeting crucial milestones; the specific conditions of fees and other incentives for milestone accomplishment will be set during the final negotiations prior to award.

GENERIC MICROBICIDE PRODUCTION MILESTONES.

- A. Synthesis/production of test agent(s)
- B. In vitro activity
- C. Development of formulated product
- D. Assessment in Rabbit Vaginal Irritation Model
- E. Demonstration of biologic plausibility/efficacy in an animal model, if relevant
- F. Selection of Microbicide Candidate/Decision to Start GMP Production Process Development

- G. Preparation/Submission of FDA Topical Microbicide Team pre-IND meeting materials
- H. Contact DAIDS for approval of Phase I Clinical Trial Concept (if not conducting trial with support from HMDDT)
- I. Completion of GMP Process Development and Production of GMP Pilot Lots
- J. Initiation of IND – Enabling Studies
 - a. Toxicology
 - b. Other
- K. Pre-IND Meeting
- L. Submit Phase I Protocol to DAIDS
- M. Completion of IND – Enabling Studies
- N. IND Filing
- O. Phase I Clinical Trial Initiation
- P. Phase I Clinical Trial Completion
- Q. Evaluation of Safety and Acceptability Data from Phase I Clinical Trial
- R. Decision on Proceeding with Phase II/Ib/III Clinical Trials
- S. Plan the Phase II/Ib/III Clinical Trial

**Reporting Requirements and Other Deliverables
HIV Microbicide Design and Development Teams
RFP DAIDS-04-04**

The Contractor is required to formally report progress once per year, through submission of a written Technical Report, and once by holding a formal Site Visit review to be attended by appropriate NIAID contract staff and program officials, and the External Steering Committee of the Team. The Contractor is also required to submit Goals and Milestones Achievement Reports during the contract period at appropriate times. Distribution of written reports is listed below in E.

A. Strategic Research Plan and updates to be approved the Project Officer.

- a. key development objectives and a detailed work plan describing proposed time schedules for achieving Contract objectives and milestones, and maintaining quality control over the implementation and operation of the Contract
- b. a plan delineating how decisions to proceed or not proceed will be made (i.e. specific qualitative and quantitative criteria for advancement of a microbicide candidate(s) through each stage of preclinical, including IND-enabling, product development and Phase I safety evaluation)
- c. plans for GMP microbicide lot production and packaging and for obtaining the necessary regulatory and human subjects approvals to proceed (**See Note to Offeror #7**)
- d. Specific Microbicide Production Milestones (**See Note to Offeror #9**)
- e. Goals and Milestones Achievement Reports. Since the payment of contract fee portions will be tied to the accomplishment of negotiated, predetermined goals and milestones, the Contractor will submit Goals and Milestones Achievement Reports during the contract period as appropriate. The original shall be submitted to the Contracting Officer, and two (2) copies (one hard copy and a copy in a digital medium) to the Project Officer. Each report must consist of:

1. A cover page

2. Reports shall include but not be limited to the following:

Section A – An introduction covering the goal or milestone.

Section B – A description of the results. Description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data accumulated to date under the goal or milestone. When appropriate this report should detail specific requests and approvals for the conduct of human trials.

- B. Clinical Trials Protocol(s). NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-supported studies. Therefore, as described in the NIAID Clinical Terms of Award (<http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf>), the Contractor shall develop a protocol for each clinical trial and submit it for approval by the NIAID Prevention Science Review Committee (PSRC). Protocols should include a description of the product, plans for preclinical toxicology and/or results, research design and protocol development including definition of objectives and approaches, planning, sample informed consent, implementation, participant recruitment and follow-up, data collection, quality control, data and safety monitoring, final data analysis and interpretation, and publication of results. Final approval of this protocol must take place prior to participant enrollment. [For trials to be conducted through the DAIDS-sponsored HIV Prevention Trial Network (HPTN), the protocol should be developed in conjunction with the HPTN.]

C. Annual Technical Report. By the fifteenth working day of the twelfth month of each Contract year, the Contractor shall submit an Annual Technical Progress Report as described below. The original shall be submitted to the Contracting Officer, and two (2) copies (one hard copy and one copy in a digital medium) to the Project Officer. The report should be factual and concise and consist of the following:

1. A cover page
2. Reports shall include but not be limited to the following:

Section A – An introduction covering the purpose and scope of the Contract effort

Section B – A description of overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the reporting period. The description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data accumulated to date under the project. Special emphasis shall be placed on goals or milestones that were reached, or problems that were encountered that prevented reaching a scheduled goal or milestone during the reporting period and how those problems were/will be addressed, and requests and approvals to conduct human trials.

Section C – A summary of the proposed goals and milestones for the duration of the Contract, including any proposed revisions based on results generated to date. Since the payment of contract fee portions will be tied to the accomplishment of negotiated, predetermined goals and milestones, the Contractor will submit Goals and Milestones Achievement Reports during the contract period as appropriate. The original shall be submitted to the Contracting Officer, and two (2) copies (one hard copy and a copy in a digital medium) to the Project Officer.

D. Annual Site Visit and Report. At the middle (6 month mark) of each contract year, the Contractor shall host, for NIAID Contract and Program staff and their External Advisory Board, a site visit. The Contractor's Principal Investigator and all co-investigators shall attend this meeting. An update and summary of results generated on each sub-project shall be presented by the co-investigator and/or other pertinent staff. These presentations shall include summaries of all goals or milestones reached during the review period and include a description of all problems encountered that will impact the achievement of particular goals and milestones as outlined in the Contractor's research plan. The Principal Investigator, co-investigator and staff representing each project and sub-project shall describe goals and milestones and development objectives for the coming year. Additionally, application of the policies and procedures for monitoring the direction of specific projects shall be presented. For Contractors with foreign subcontracts, this annual site visit will also report details about approvals for manufacturing or testing that have been obtained from both the U.S. and foreign governments. A report of the plan for, and results of, this site visit shall be prepared by the Contractor and submitted to the Project Officer (in hard copy and digital medium) and the Contracting Officer (original hard copy) within one month of the date of the meeting.

E. Final Technical Report. The Contractor shall submit the final report documents, two (2) copies (one hard copy and one copy in a digital medium) to the Project Officer, and the original to the Contracting Officer, which shall summarize the results of the entire contract work for the complete performance period, and shall include the specifications of the optimized HIV microbicide product developed during the course of this Contract. These specifications shall include: (1) the identity of the active agent(s) in the final product, (2) a detailed description of the manipulations used in the microbicide design, (3) a detailed description of all processes used to synthesize, expand, attenuate, inactivate, or purify the final microbicide product(s), (4) a detailed description of the formulation used in the delivery of the final optimized product(s), (5) a detailed description of the suggested application schedule to be used for optimal protection in humans, (6) evidence that the microbicide product(s) can be manufactured and packaged under GMP/GLP conditions for use in human prevention trials, and 7) patent filings. In addition, the Contractor shall indicate whether any INDs

were filed in relation to microbicide products developed during the course of the Contract, and provide a description of the IND and the results of the filings. For Contractors with foreign subcontracts this report shall include details concerning approvals for manufacturing or testing that have been obtained for or by the foreign subcontractors. The final report shall be submitted by the completion date of the Contract.

F. Technical Reports Distribution

<u>Type of Report</u>	<u>No. of Copies</u>	<u>Addressee/Distribution</u>	<u>Due Dates</u>
Strategic Research Plan	*3	Project Officer VPRP, Division of AIDS, NIAID 6700-B Rockledge Drive Room 5135 MSC 7628 Bethesda, MD 20892-7628	Bi-annual or as requested by the Project Officer
Goals and Milestones Achievement Reports	Original	Contracting Officer CMP, DEA, NIAID 6700-B Rockledge Drive Room 3214 MSC 7612 Bethesda, MD 20892-7612	same as above
Annual Technical Report	*1	Same as Project Officer above	yearly
Annual Technical Report	Original	Same as Contracting Officer above	yearly
Annual Site Visit Review Report	*1	Same as Project Officer above	yearly
Annual Site Visit Review Report	Original	Same as Contracting Officer above	yearly
Final Technical Report	*1	Same as Project Officer above	completion date
Final Technical Report	Original	Same as Contracting Officer above	completion date

* plus one copy on 3.5 inch, high density computer diskette or other digital medium approved by the Project Officer

G. If the Contractor is unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

<http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm>

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following 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 URL: <http://www.arnet.gov/far/>.

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

<u>FAR Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-10	Mar 1997	Incentive Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	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
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-25	Feb 2002	Prompt Payment, Alternate I (Feb 2002)
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	July 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)

52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in Article B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

<u>HHSAR Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 4/2003]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause 52.219-16, LIQUIDATED DAMAGES--SUBCONTRACTING PLAN (JANUARY 1999) is deleted in its entirety.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefor. **[Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), 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.

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

FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference.....

[] Offeror elects to waive the evaluation preference."

FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (MAY 2001).

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10% percent to the price of all offers, except--..."

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

FAR 52.227-14, Rights in Data - General (JUNE 1987)

FAR 52.242-3, Penalties for Unallowable Costs (OCTOBER 1995).

FAR 52.243-2, Changes--Cost Reimbursement (AUGUST 1987), Alternate V (APRIL 1984).

FAR 52.247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997).

b. **DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:**

HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

c. **NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:**

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

NIH(RC)-11, Research Patient Care Costs (4/1/84).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

(a) **Definitions.** As used in this clause--

Commercial item has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or non-developmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

- (i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
- (iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
- (iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
- (v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flow-down not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PROPOSAL SUBMISSION INSTRUCTIONS – see: <http://www.niaid.nih.gov/contract/eproposal.htm>

PROPOSAL SUBMISSION: NUMBER OF COPIES AND PAGE LIMITATIONS (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON OR BEFORE June 30, 2004](Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMP's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

<http://www.niaid.nih.gov/contract/ref.htm>

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- Technical Proposal Cover Sheet
- NIH-1688-1, Project Objectives
- Technical Proposal Cost Information
- Summary of Related Activities
- Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]
- Government Notice for Handling Proposals
- Targeted/Planned Enrollment Table
- Annual Technical Progress Report Format for Each Study

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format *[if applicable]*
- Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
- Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- NIH (RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- NIH (RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- Safety and Health, HHSAR Clause 352.223-70
- Privacy Act System of Records
- Report of Government Owned, Contractor Held Property
- Disclosure of Lobbying Activities, OMB Form LLL
- Target/Planned Enrollment Table
- Inclusion Enrollment Report

PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE

Please refer to <http://www.niaid.nih.gov/contract/eproposal.htm> for delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided at the above-referenced weblink. **You must certify that both the original paper and electronic versions of the proposal are identical.**

The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.

If you experience difficulty or are unable to transmit, you may submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

SUBMISSION OF ONLY ELECTRONIC PROPOSALS WITHOUT PAPER COPIES IS NOT ACCEPTABLE.

NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) unbound signed original. Thirty (30) unbound copies.	N/A	N/A
Business Proposal	One (1) unbound signed original. Five (5) unbound copies.	N/A	N/A
Representations and Certifications	One (1) Original required to be submitted with the Original Business Proposal. (Extra copies are optional.)	N/A	N/A
Proposal Appendices	Thirty (30) unbound copies of all materials not available electronically (i.e. SOPs, Pertinent Manuals, Non-scannable Figures or Data, and Letters of Collaboration/Intent).	Included in page limits.	N/A

WARNING: You are advised to read and carefully follow the instructions listed in each RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-04-04
RFP Title: Microbicide Design and Development Teams

Please review the attached Request for Proposal. Furnish the information requested below and return this page by June 30, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

- DO INTEND TO SUBMIT A PROPOSAL
- DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
 CMP, NIAID, NIH
 Room 3214
 6700-B Rockledge Drive, MSC 7612
 Bethesda, MD 20892-7612
 Attn: Donald E. Collie
 RFP-NIH-NIAID- DAIDS-04-04
 FAX# (301) 480-5253
 Email: dc128b@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions.* As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing," "writing," or *"written"* any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.*

- (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

- (ii) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--
 - (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
 - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
 - (3) It is the only proposal received.
 - (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
 - (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
 - (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
 - (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
 - (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
 - (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
 - (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
 - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

- (e) *Restriction on disclosure and use of data.*
 - (1) The proposal submitted in response to this request 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. 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. The legend reads:

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.

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.

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 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.

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. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

“Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation.”

- (3) Offerors are cautioned that proposals submitted with 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.

(f) *Contract award.*

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in proposals received.
- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
 - (i) The overall evaluated cost or price and technical rating of the successful offeror;
 - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iii) A summary of the rationale for award; and
 - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 54171.
- (2) The small business size standard is 500.

c. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that MULTIPLE AWARDS will be made from this solicitation and that the award(s) will be made on/about May 16, 2005.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT PLUS INCENTIVE FEE type COMPLETION contract with a PERIOD OF PERFORMANCE OF 5 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. 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.

e. 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 the Project Officer or other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

f. 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.

g. COMPARATIVE IMPORTANCE OF PROPOSALS

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

h. PREPARATION COSTS

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

i. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(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:

Contracting Officer: [See Block 15 of RFP Cover Page]
Address: [See Block 9 of RFP Cover Page]

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

(End of Provision)

j. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

k. USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

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.

(1) Contract Type and General Clauses

It is contemplated that a [cost-reimbursement (completion/level of effort)/fixed price] type contract will be awarded. (See General Information) 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.

(2) Authorized Official and Submission of Proposal

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 addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J, hereof. 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:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

a. Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an Institution of Higher Education: The form MUST be completed in its entirety.
- For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "INSTRUCTIONS:"

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

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 and as specified in SECTION J, List of Attachments.

(3) Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

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 Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS.) 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.

(5) Alternate Proposals

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.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(1) Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(2) Use of the Metric System of Measurement

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.

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:

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).

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.

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.

(3) **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(a) through (f)] shall be addressed in SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

- a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.
- b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.
- c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
- d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.
- e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.
- f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at <http://ohrp.osophs.dhhs.gov/> Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.*

- **Instructions to Offerors Regarding Protection of Human Subjects**

****(Note: The requirements in this paragraph (10), may be supplemented when necessary, based on the specific requirements of the solicitation.) ****

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(4) Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) Announcement dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/>. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_prof_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one-sentence description of the program that the replacement has completed.

(5) Inclusion of Women and Minorities in Research Involving Human Subjects

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), *and applies to research subjects of all ages*.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (<http://www.nih.gov/news/crp/97report/execsum.htm>).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: <http://www.whitehouse.gov/OMB/fedreg/ombdir15.html>

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you

collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**¹ require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm,
Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

¹See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm for the Definition of an "NIH-Defined Phase III clinical trial.

(6) Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. **(See examples of Justifications for Exclusion of Children below).** For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
 - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
 - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
 - A separate, age-specific study in children is warranted and preferable. Examples include:
- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or

- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(7) Data and Safety Monitoring in Clinical Trials

**** (Note: The following language may be modified to incorporate an IC's alternate and comparable approach to expressing the NIH policy regarding Data and Safety Monitoring in Clinical Trials.) ****

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>
<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety-monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at <http://grants.nih.gov/grants/guide/notice-files/not98-084.html> describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(8) Care of Live Vertebrate Animals

- a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

- b. The following information must be included in the offeror's technical proposal:

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;
- a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and

- a description of any euthanasia method to be used.
- c. If an Animal Assurance is already in place, the offeror's proposal shall include:
- The Animal Welfare Assurance number.
 - The date last certified by OLAW. (i.e. assurance letter from OLAW)
 - Evidence of recent AAALAC Accreditation.

(9) Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>.

(10) Privacy Act (Treatment of Proposal Information)

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.

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 P.L. 92-218, as amended.

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.

Failure to provide any or all of the requested information may result in a less than adequate review.

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.

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.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.

- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(11) Selection of Offerors

- a) The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each 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.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-

- (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

- (2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The Institute 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 the Institute's requirements. Synopses of awards exceeding \$25,000 will be published in the FedBizOpps.

(12) Small Business Subcontracting Plan

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 Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation [See Section J, Attachments, for an example of such a plan].

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.
- 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.
- c) The offeror understands that:
 - (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 Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses 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 Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
- (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, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
- (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses 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, and the Sample Subcontracting Plan which is provided as an Attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

- 23% Small Business
- 5% Small Disadvantaged Business
- 3% Women-Owned Small Business
- 5% HUBZone Small Business
- 3% Veteran-Owned Small Business
- 3% Service-Disabled Veteran-Owned Small Business

(13) HUBZone Small Business Concerns

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 ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

(14) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated

on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination is:
<http://www.amet.gov/References/sdbadjustments.htm>

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation is **not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime	10%	\$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	\$150,000

***NOTE:** FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(15) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(16) Salary Rate Limitation in Fiscal Year 2004

Offerors are advised that pursuant to P.L. 108-199, no NIH Fiscal Year 2004 (October 1, 2003 - September 30, 2004) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-199 applies only to Fiscal Year 2004 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-199 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

LINK TO EXECUTIVE SCHEDULE SALARIES: <<http://www.opm.gov/oca/PAYRATES/index.htm>>

Note to Offerors: The current Fiscal Year 2004 Executive Level I Salary should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2004 Executive Level I Salary rates.

(17) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) 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.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) 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.

- (d) 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.
- (e) 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.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - 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.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) 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.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
 - (ii) monitoring of research by independent reviewers;
 - (iii) modification of the research plan;
 - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - (v) divestiture of significant financial interests; or
 - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) 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.

(18) ROTC Access and Federal Military Recruiting on Campus

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.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) 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.

(19) Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more 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. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- c) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- d) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- e) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

(20) Prohibition on Contractor Involvement with Terrorist Activities

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under any resultant contract(s).

(21) Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDC's that can be found at <http://www.cdc.gov/od/ohs/lrsat.htm> and NIH's OBA that can be found at <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html>.

(22) Guidance Regarding Federal Government Collaborations

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or appearance of a conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter **must** be signed by both the designated agency ethics official and the head of the agency (or their respective designees). The

NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or appearance of a conflict of interest.

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach 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. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a) Statement of Work

(1) Objectives

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.

(2) Approach

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.

(3) Methods

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.

(4) Schedule

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.

b) Personnel

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.

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.

(1) Principal Investigator/Project Director

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.

(2) Other Investigators

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.

(3) Additional Personnel

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:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government'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 project objectives.
- b) 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 the information contained in the offeror's proposal only.

(4) Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

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.

(2) Information Other than Cost or Pricing Data

- a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

(3) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

- (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

- (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

- (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

- (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

- (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

- (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

- (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
- (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
- (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
 - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

(4) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

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.

b) **Organizational Experience Related to the RFP**

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.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

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 of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission 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 factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(5) Other Administrative Data

a) **Property**

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

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**

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.

- (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.

c) **Financial Capacity**

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.

d) **Incremental Funding**

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:

HHSAR 352.232-75, Incremental Funding (January 2001)

- (a) 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 the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted 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.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

(This is applicable if you are a commercial organization.)

- (a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(6) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.

- f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm>

(7) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(8) Representations and Certifications

One copy of the Representations and Certifications attached as Section K 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.

(9) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(10) Certification of Visa's for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

(11) Guidance Regarding Federal Government Collaborations

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or potential conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter **must** be signed by **both** the agency's ethics official and the head of the agency (or his/her designate). The NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or apparent conflict of interest.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to the Offeror(s) whose proposal provides the best overall value to the Government.

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 criteria listed below.

2. MANDATORY QUALIFICATION CRITERIA

The following qualification criterion establishes documentation that MUST be submitted by the closing date and time of this RFP. Proposals that do not contain this documentation will not be evaluated and will not be considered further for award.

Offerors MUST provide one, or more as applicable, draft agreement(s) duly executed by the following persons:

- The proposed Principle Investigator and an official authorized to bind the Principal Investigators organization
- The proposed co-principle investigator and an official authorized to bind the co-Principals organization
- Any other personnel who are likely to produce intellectual property and an official authorized to bind their organization

The agreement will outline procedures to be used for (1) obtaining patent coverage and licensing of the resulting HIV microbicide(s), and (2) procedures to be followed for the resolution of potential legal issues that may arise. Offerors should discuss potential legal issues/disputes such as ownership, licensing and rights to intellectual property developed during the conduct of the contract statement of work. In addition offerors are encouraged to present other legal issues that demonstrate the offerors understanding of the complexity of this project.

3. TECHNICAL PROPOSAL EVALUATION CRITERIA

Proposals submitted in response to this RFP will be evaluated based on the following factors that are listed and weighted in order of their relative importance. Proposals will be judged solely on the written material provided by the Offeror.

1. Technical Approach

Points: 40

Suitability and feasibility of:

- a) the proposed goals and milestones for optimizing the efficacy and safety of the microbicide concept
- b) the methods and procedures for implementing the scientific plans and achieving the proposed goals and milestones
- c) the appropriateness and adequacy of the experimental approach and methodologies proposed, and assays to detect inhibitory potency and evaluate safety
- d) the proposed time schedule for achieving contract objectives and milestones
- e) the proposed qualitative and quantitative criteria that will be used in deciding when to proceed to the next phase of development toward candidate microbicide product
- f) the plans for modifying the goals and milestones based on adverse experimental or production results, or on new scientific findings along the development path
- g) the adequacy and feasibility of any proposed plans for conducting and managing clinical trials, (including international settings, if planned) including protection of human subjects from research risks, representation of

appropriate genders, racial/ethnic and age groups, data and safety monitoring and reporting, and valid analysis of data

h) proposed animal studies

2. Scientific Rationale

Points: 20

- a) Soundness of the scientific rationale of the proposed microbicide concept, including selection of components, formulation, and delivery.
- b) Rationale of the likelihood of obtaining the envisioned product
- c) Critical rationale for the suitability and applicability of the envisioned product to worldwide use, including feasibility of large-scale manufacture and widespread acceptance of envisioned product
- d) Uniqueness of the approach to surmounting obstacles to HIV microbicide development

3. Qualifications and Availability of Proposed Scientific and Management Staff

Points: 20

a) Leadership and Management Structure

Proposed scientific and administrative leadership, and project management of and by the Team. This must include the documented training, expertise, leadership, and availability of a Principal Investigator and a Project Manager. The strategy and rationale for the structure of the team components, staffing strategy (including use of subcontracts, consultants, collaborators), and administrative framework, indicating clear lines of authority and responsibility for the project's management, must be described. If the Team elects to have both a scientific and a management leader, the proposal must also include the documented training, experience, and leadership of the management expert. The overall competence of the Principal Investigator and the surrounding leadership to successfully manage a project of this size and complexity must also be illustrated.

b) Scientific and Technical Staff

Documented training, experience and availability of the proposed other professionals, research, technical, management, and support staff, and their documented capability to perform their roles in the proposed studies, and expertise in similar projects, including experience with international clinical studies if appropriate to proposal and GLP/GMP. Delineation of responsibilities and time commitment of the professional and technical staff and consultants.

c) Subcontractors

Documented training, experience and availability of any proposed subcontractor(s), their documented capability to perform the proposed work, including GLP/GMP, and expertise in similar projects. The logistical adequacy of the plan for use of the subcontractor(s) in the conduct of the project, including the time commitments of the professional and technical staff. Quality and feasibility of the plan to identify the need to add, replace, or remove the subcontractor's scientific staff, dependent on the progress or change in scientific direction. Adequacy of plans for evaluating the performance of subcontractors.

4. Facilities and Resources

Points: 20

Documented availability and adequacy of facilities, equipment, and resources necessary to safely carry out all phases of the proposed project including:

- a) a detailed laboratory layout
- b) information regarding ownership/lease of the facility, including its demonstrated availability for the duration of the contract and process for prioritization of projects including obtaining, adding, or deleting facilities as necessary due to progress during the course of product development
- c) demonstrated compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and other hazardous materials
- d) capacity to perform regulatory- and human subjects protection-compliant clinical trial(s), or a letter-of-interest from the appropriate NIAID-sponsored trial network in performing a clinical trial with the Offeror's proposed microbicide product(s). Capacity should be shown for the prime and all subcontractors.
- e) capacity to perform FDA-required safety, potency, and other pre-clinical studies
- f) capacity for production and packaging of the microbicide product under GMP/GLP conditions

TOTAL:

100 Points

3. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be used in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- (a) Complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for the arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.
- (b) Extent of participation of SDB concerns in terms of the value of the total acquisition.

4. HUMAN SUBJECT EVALUATION

Those Offerors planning to use an NIAID-sponsored network to perform clinical trials of their product(s) may substitute a "letter-of-interest" from the appropriate network for Proposal detail in response to the DHHS-mandated guidelines for human subject protection and evaluation described below. Offerors planning to conduct clinical trials themselves under this Contract must satisfy these guidelines.

Therefore, if, this research project involves human subjects, NIH Policy requires (see <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>):

(a) **Protection of Human Subjects from Research Risks**

The Offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If concerns are identified and the Offeror is included in the competitive range, the Offeror will be afforded the opportunity to further discuss and/or clarify the Team's position during discussions and in the Team's Final Proposal Revision (FPR). If, after discussions, concerns still exist, the Offeror's proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The Offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work for the solicitations specific requirements for data and safety monitoring.

The NIAID will evaluate the acceptability of the proposed data and safety-monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. If the information provided about Data and Safety Monitoring is determined to be inadequate and the Offeror is included in the competitive range, the Offeror will be afforded the opportunity to further discuss and/or clarify the Team's plan during discussions and in the Team's Final Proposal Revision (FPR). If, after discussions, the plan is considered inadequate, the Offeror's proposal may not be considered further for award.

(c) Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NOTE: Additional requirements for phase III clinical trials are not included. Support for phase III studies will not be funded under this solicitation.

The proposal must also address the proposed outreach programs for recruiting women and minorities as participants. Where the Offeror determines that inclusion of women and minority populations is not feasible, the Offeror must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and the Offeror is included in the competitive range, the Offeror will be afforded the opportunity to further discuss, clarify, or modify the Team's plan for inclusion in the Team's Final Proposal Revision (FPR). If the Offeror's exclusion position is still considered unacceptable by the Government after discussions, the Offeror's proposal may not be considered further for award.

(d) Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are scientific and ethical reasons not to include them. The Offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of child is appropriate, the proposal must also address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

5. PAST PERFORMANCE FACTOR

An evaluation of Offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the Offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the Offeror as it relates to all acquisition requirements, such as the Offeror's record of performing according to specifications, including standards of good workmanship; the Offeror's record of controlling and forecasting costs; the Offeror's adherence to contract schedules, including the administrative aspects of performance; the Offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the Offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror.