U.S. Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DAIDS-08-19

"SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. http://www.fedbizopps.gov/**		
2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1** **NOTE: The issuance of this solicitation does not commit the government to an award.**		
3. **Issue Date:** May 30, 2007	4. **Due Date:** July 30, 2007 **Time:** 4:00 P.M., Local Time	5. **Small Bus. Set-Aside:** [X]Yes [ ] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS: 541710** (See Part IV, Section L.)
6. **Just In Time:** [X] No [ ] Yes (See Part IV, Section L.)	7. **Number of Awards:** [X] Only 1 Award [ ] Multiple Awards	8. **Technical Proposal Page Limits:** [ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)
9. **Issued By:** Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	10. [X] **NIAID reserves the right to make awards without discussion.** 11. ***Options:*** **[X] No** **[ ] Yes** (See Part IV, Section L.)	12. **Period of Performance:** February 16, 2008 through February 15, 2015
13. **Primary Point of Contact:** **Name : Anita Hughes** **Phone:** 301-496-0612 **Fax:** 301-402-0972 E-Mail: anhughes@niaid.nih.gov	14. **Secondary Point of Contact:** **Name: Eileen Webster-Cissel** **Phone:** 301-496-0612 **Fax:** 301-402-0972 E-Mail: webstere@niaid.nih.gov	15. **Protest Officer:** Charles Grewe Director, OA **Address (see Block 9.)**
16. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.		
17. **Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)**		
18. **DELIVERY ADDRESS INFORMATION**		
19. **Hand Delivery or Overnight Service:** Anita Hughes, Contract Specialist Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	20. **U.S. Postal Service or an Express Delivery Service** Anita Hughes, Contract Specialist Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612	
21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original 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 FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.		

Updated thru FAC 2005-14 (11/22/2006)

DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is small scale synthesis of compounds in quantities required for testing in either in vitro screens or animals, and large scale synthesis of compounds for early Phase I clinical studies.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

The following clause will be included in the Advance Understandings Article of any resultant contract:

Confidentiality of Information and Intellectual Property

Confidentiality of Information
Information and data provided to or generated by the Contractor under this contract shall be treated confidentially and protected by an Advance Understanding to be included in the resulting contract and worded as follows:

"Because there is a likelihood that the Contractor will be utilizing and evaluating materials provided to the Government by a third party Provider, it is essential to include provisions that will protect the proprietary rights of the Provider. These materials generally are supplied to the Government as proprietary and confidential. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Provider.

All information provided by the Provider or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for review and written approval by the Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 20 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Provider of the drug substance for their review. When the Provider does not consent to publication of the manuscript or abstract, the Project Officer shall withhold approval to publish in accordance with the terms and conditions of any existing Evaluation Agreement or Material Transfer Agreement between NIAID and the Provider. NIAID will use its best efforts to assist and expedite the review and approval process by the Provider."

Intellectual Property
Contractors acknowledge that:

* If needed for the project, Contractor is solely responsible for the timely acquisition of any proprietary rights, including intellectual property rights, and all materials appropriate for Contractor to perform the project;

* Contractor acknowledges that prior to, during, and subsequent to the award, the U.S. Government is not required to obtain for Contractor any proprietary rights, including intellectual property rights, or any materials needed by Contractor to perform the project;

* Contractor acknowledges the requirement to report to the U.S. Government all inventions made in the performance of the project, as specified at 35 U.S.C. Sect. 202 (Bayh-Dole Act).

Contractor is encouraged to reach early consensus with any proposed partners regarding any appropriate intellectual property or other legal issues that may arise during the project. In addition, Contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit. Finally, Contractor is expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms consistent with laws, regulations, and NIH policies.

Shall patents arise from this contract, they will be subject to laws governing federally funded inventions. The Government retains, for government purposes, a non-exclusive, irrevocable, paid-up license to federally funded inventions.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated March 22, 2007, attached hereto and made a part of this Solicitation *(See SECTION J - List of Attachments, Attachment 3, Statement of Work).*

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *(Please refer to Attachment 4, Reporting Requirements and Deliveries, of this solicitation).*

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. Thereafter, reports shall be due on or before the thirty calendar day following the reporting period. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Disesaes
National Institutes of Health
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892 - 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer designated in ARTICLE G.1. is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items specified in the Delivery Schedule which are described in SECTION C of this contract. *(Please refer to Attachment 4, Reporting Requirements and Deliveries, of this solicitation).*

b. Deliveries required by the contractor shall be made F.o.b. destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within consignees Premises (April 1984) [and any specifications stated in SECTION D, PACKAGING AND MARKING AND SHIPPING, of this contract] to the address/addressee listed below: *(Please refer to Attachment 4, Reporting Requirements and Deliveries, of this solicitation).*

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with Alternate I (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

[The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.]

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the

diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

[To be specified in Contract]

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR 32.9, Prompt Payment.

(1) Invoices/financing requests shall be submitted as follows:

One original to the following designated billing office:

National Institutes of Health
Office of Financial Management
Commercial Contracts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

(2) In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all invoices/financing requests:

(a) Name of the Office of Acquisitions to which you are submitting the invoice/financing request: **NIAID**
(b) Central Point of Distribution: For the purpose of this contract, the Central Point of Distribution is **NIAID OA Invoices**.
(c) Vendor Identificaiton Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of the Standard Form 26. **(Note: This only applies to new contracts awarded on/after June 4, 2007, and any existing contract modified to include the number).**
(d) DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract (Standard Form 26).
(e) Identification of whether payment is to be made using a two-way or three-way match. The contract requires a **two-way** match.

b. Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-6088.

ARTICLE G.4. INDIRECT COST RATES *(This only applies if the successful offeror is a profit making organization)*

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted biannually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:
http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.3. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.4. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of

Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.5. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.6. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" 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, patient 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. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by

the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. **Public Law and Section No.***	**Fiscal Year***	**Dollar Amount of Salary Limitation***

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

[*Applicable information to be included at award]

ARTICLE H.7. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. ."

ARTICLE H.8. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.9. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eere.energy.gov/

ARTICLE H.10. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available athttp://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

The complete listing of these clauses may be accessed at:

http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

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 substitution(s) will be made part of the resultant contract:

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

Alternate IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

FAR Clauses **52.219-9, Small Business Subcontracting Plan** (September 2006), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), 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.]***

Alternate I (February 2002), of FAR Clause **52.232-25**, **Prompt Payment** (February 2002) is deleted.

HHSAR Clause **352.249-14, Excusable Delays** (April 1984) is deleted in its entirety and FAR Clause **52.249-14, Excusable Delays** (April 1984) is substituted therefor.

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

(1) FAR Clause **52.216-17, Waiver of Facilities Capital Cost of Money (October** 1997).

(2) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....
[ ] Offeror elects to waive the evaluation preference."

(3) FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (June 2003).

(4) FAR Clause **52.219-14**, **Limitations on Subcontracting** (December 1996)

(5) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(4) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

(5) FAR Clause **52.237-3, Continuity of Services** (January 1991).

(6) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

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

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2006).

(2) HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).

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

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

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

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:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Reporting Requirements and Deliveries	See Attachment Section at the end of this RFP
Attachment 5:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 6:	Additional Business Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 7:	DAIDS Material Evaluation Agreement	See Attachment Section at the end of this RFP
Attachment 8:	Government Furnished Equipment	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 9:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 11:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf
Attachment 12:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 13:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 14:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls

Attachment 15:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 16:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 17:	Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	http://farsite.hill.af.mil/reghtml/regs/other/hhsar/352.htm#P70_8260
Attachment 19:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 20:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and

2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:

   http://rcb.cancer.gov/rcb-internet/wkf/sectionk.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.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2004)]

(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"* means 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, and
(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) (A) 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).

(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 statements, specifying the particular portions of the proposal which are to be restricted:

> 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 must 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 statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(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) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(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. **NOTICE OF SMALL BUSINESS SET-ASIDE**

(1) **General**. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(2) **Definitions**. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

c. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about February 16, 2008.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement completion type contract with a period of performance of seven years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **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.

The North American Industry Classification System (NAICS) code for this acquisition is 541710 . The small business size standard is 500 employees .

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 6 full time equivalents (FTE). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **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.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **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.

i. **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 are 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.

j. **PREPARATION COSTS**

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

k. **SERVICE OF PROTEST** (SEPTEMBER 2006) - 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 Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Charles Grewe
Director, Office of Acquisitions, DEA
National Institute of Allergy and Infectious Disesaes
National Institutes of Health
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892 - 7612

(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)

l. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70 (January 2006)

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 appears to offer the best value 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)

2. INSTRUCTIONS TO OFFERORS

a. **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 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 addresses, 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, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

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 12 entitled, TECHNICAL PROPOSAL COST SUMMARY). 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) **Uniform Resource Locators (URLs) in Contract Proposals**

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

(6) **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.

(7) **Evaluation of Proposals**

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

(8) **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.

(9) **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 procurement, 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.

(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 NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID 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 source 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 NIAID 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 NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(12) **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.

(13) **Past Performance Information**

a) Offerors shall submit the following information as part of their business proposal.

A list of the last 5 contracts completed during the past 3 years and the last 3 contracts awarded currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract that exceeds $650,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(14) **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.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

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

c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b. **TECHNICAL PROPOSAL INSTRUCTIONS** ***(Offerors are advised to refer to Attachment 5, Additional 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) **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:"**

b) **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.

c) **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) Single 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 SECTION M - Evaluation Factors for Award of this solicitation.

(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.

c. **BUSINESS PROPOSAL INSTRUCTIONS** ***(Offerors are advised to refer to Attachment 6, Additional 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) **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;

2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) **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.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**
Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**
Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**
Include parts, components, assemblies, and services that are to be produced or

performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**
   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**
   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**
   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**
   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**
   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**
   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**
    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

(4) **Salary Rate Limitation in Fiscal Year 2007**

Offerors are advised that pursuant to P.L. 110-005**, no NIH Fiscal Year 2007 (October 1, 2006 - September 30, 2007) 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, patient 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. 110-005** applies only to Fiscal Year 2007 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 limitation also applies to individuals proposed under subcontracts; however, it does not apply to consultants. P.L. 110-005** 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 other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO FY 07 EXECUTIVE SCHEDULE SALARIES:
http://www.opm.gov/oca/07tables/html/ex.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.*

***Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY 2007. The Executive Level I annual salary rate was $183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive Level I salary rate increased to $186,600.*

(5) **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.

(6) **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.

(7) **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, "Contractor's 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:

Incremental Funding, HHSAR 352.232-75, (January 2006)

(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 as specified in FAR 52.232-22. 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. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

e) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

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

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) 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.

(8) **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/FDPclausecover.htm

(9) **Proposer's Annual Financial Report**

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

(10) **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

(11) **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.

SECTION M - EVALUATION FACTORS FOR AWARD

a. 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 past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price 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/price. The Government intends to make an award to that offeror 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.

OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO ATTACHMNET 5 – Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATON RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

b. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. The offeror shall include all information which documents and/or supports the qualification criteria in one clearly marked section of its proposal.

> All Offerors shall be registered with the United States Food and Drug Administration (FDA) as a manufacturer of bulk drugs. The facilities shall meet FDA standards in accordance with the current Good Manufacturing Practice (cGMP) guidelines. The Offeror must provide documented proof of FDA registration and most recent routine FDA inspection(s). Moreover, the Offeror must be in compliance with FDA requirements during the entire course of the contract period. The proposal must describe specific examples of products manufactured by the Offeror, which have been used in clinical trials.

The qualification criteria establishes conditions that must be met at the time of submission of the original proposal in order for your proposal to be considered any further for award.

c. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA **WEIGHT**

CRITERION 1: Scientific and Professional Personnel **40 points**

1. Principal Investigator: Relevance and extent of recent experience and scientific accomplishments in synthetic organic chemistry, in modification of synthetic routes for large scale synthesis, qualifications in directing a project of similar scope and complexity, and availability for assignment. Knowledge and experience in generating and interpreting spectroscopic and analytic data.

2. Key Scientific and Professional Personnel: Relevance and extent of experience of other investigators, based on recent examples of pertinent accomplishments in small and large scale organic synthesis, experience in purification and characterization of intermediates and target compounds, knowledge and experience in generating spectroscopic and analytic data, evidence of team work experience and documented availability.

3. Experience, training, and qualifications of all personnel in the safety and handling of chemicals of a hazardous nature.

CRITERION 2: Technical Approach **30 points**

The scientific soundness of the approach and awareness of potential problems, as exhibited in the discussion of:

1. approaches to small- and large-scale synthesis of compounds

2. three examples of large scale synthesis of known organic compounds previously synthesized by the organization with the involvement of some of the proposed team members, including problems encountered and the solutions implemented

3. plans for monitoring the synthetic processes, and the characterization of final products and key intermediates with respect to identity and purity

4. documentation of the ability to synthesize compounds on a large scale in compliance with cGMP regulations

5. shipping and compliance with safety and health regulations

6. plans for acquisition and characterization of compounds through purchase or donation to be used for efficacy testing against infectious diseases relevant to AIDS

CRITERION 3: Facilities, Equipment and Other Resources **20 points**

Adequacy and documented availability of appropriate facilities including laboratory space and equipment (HPLC, IR, UV-VIS, NMR, MS) to synthesize, purify and characterize compounds on the scale requested (10 mg-1000g); availability of library

resources including on-line search capability. Controlled access areas for secure and safe storage of chemicals, synthetic reports and confidential information.

CRITERION 4: Project Management **10 points**

1. Adequacy and appropriateness of the proposed overall project organization and staffing; plans and procedures for the close monitoring, tracking, coordination and management of all contract activities, including interaction and communication with the Project Officer and Contracting Officer to ensure efficient planning, initiation, implementation, monitoring and management of all projects carried out under the contract.

2. Appropriateness and feasibility of the plans for prioritization of projects and the procedures for implementation and timely completion of projects; previous experience in timely completion of comparable tasks

3. Appropriateness and adequacy of the proposed procedures to safeguard the confidentiality and intellectual property of data and materials provided by third parties or the Government, as well as data generated by the Contractor

Total: 100 points

d. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of 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 mechnical 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.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

ATTACHMENT 1
PACKAGING AND DELIVERY OF THE PROPOSAL

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

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS **NOT** ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DAIDS-08-19**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT:
Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information. *Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.*

2. It is preferred that the Technical Proposal be submitted as *one electronic file document*.

   Note: if multiple files are submitted for either proposal, please include the name of the section in the file name.
   EXAMPLE: XYX Company-07-16-Technical-Approach-3-6-06

3. CDs should be named using the following format:

   Technical Proposal: ***Company name-RFP number-technical-date***
   Business Proposal: ***Company name-RFP number-business-date***

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	Not to Exceed 200 pages (inclusive of all Attachments and Appendices)
Business Proposal	PAPER **One (1) unbound SIGNED ORIGINAL.** **Six (6) unbound COPIES** **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

ATTACHMENT 2
PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-08-19
RFP Title: SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES

Please review the attached Request for Proposal. Furnish the information requested below and return this page by June 20, 2007. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] 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:
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: Anita Hughes
RFP-NIH-NIAID-DAIDS-08-19
FAX# (301) 402-0972
Email: anhughes@niaid.nih.gov

ATTACHMENT 3
STATEMENT OF WORK

SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES
RFP NIH-NIAID-DAIDS-08-19

BACKGROUND and INTRODUCTION:

The Division of Acquired Immunodeficiency Syndrome (DAIDS), NIAID, NIH, supports research to identify therapeutic agents for the prevention and treatment of infections with the human immunodeficiency virus (HIV) and co-infections with opportunistic pathogens, including *Mycobacterium tuberculosis*. DAIDS-sponsored researchers are actively engaged in investigating the basic biology of the targeted pathogens, identifying novel therapeutic approaches to treat diseases caused by these infectious agents, and testing therapeutic agents *in vitro* and in animal models.

Prior to evaluation in clinical trials, most experimental agents require chemical resynthesis, pharmaceutical analysis, and dosage formulation to ensure products are of sufficient quantity and quality to permit proper testing in humans. DAIDS currently uses contracts to fulfill its needs for these services. This solicitation will support the DAIDS drug development effort by accomplishing the synthesis of therapeutic agents in small and large scale amounts, some according to current Good Manufacturing Practice (cGMP) regulations of the Food and Drug Administration (FDA).

The synthesis contract was initiated in 1989 and last re-competed in 2000. This solicitation provides for the recompetition of a contract (N01-AI-05402) that was awarded to Starks Associates, Inc. for synthesis of potential therapeutic agents for treatment of infectious diseases and that will expire on February 1, 2008. The National Institute of Allergy and Infectious Diseases (NIAID) anticipates awarding a single contract for a term of seven (7) years.

Over 250 different compounds of interest to DAIDS have been synthesized to date. Compounds assigned for synthesis include heterocycles (typically containing nitrogen, oxygen, and sulfur), carbocycles, carbohydrates, nucleosides and peptides. The majority of synthesized compounds have been used by DAIDS-supported contracts for enzymatic, *in vitro*, and *in vivo* studies. Small quantities of metabolites have been synthesized for use in mechanism of action and metabolism studies and larger, bulk quantities of compounds have been synthesized for animal studies and clinical trials.

SCOPE:

The scope of this effort is small scale synthesis of compounds in quantities required for testing in either *in vitro* screens or animals, and large scale synthesis of compounds for early Phase I clinical studies. Some compounds will require synthesis in compliance with cGMP regulations. This contract will provide resources for the synthesis of promising compounds for the treatment of HIV, tuberculosis, hepatitis and other infectious diseases of relevance to the research agenda of NIAID.

TECHNICAL REQUIREMENTS:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below. The major tasks to be carried out are as follows:

1. Initial transition
2. Synthesize compounds (small scale)
3. Synthesize compounds (large scale)
4. Acquire compounds for efficacy testing
5. Ship compounds to NIAID
6. Provide facilities, equipment, and other resources
7. Final transition

The above tasks include the following detailed requirements:

1. INITIAL TRANSITION

In the event the incumbent Contractor is not successful in the recompetition, the Project Officer will provide the new Contractor with a copy of the incumbent contractor's Final Transition Plan concurrent with the contract award.

a. Within thirty (30) calendar days of the contract award, the Contractor shall submit for Project Officer review and written approval, an Initial Transition Plan and timetable for the receipt, storage, and transfer of all items in the incumbent Contractor's Final Transition Plan. The Plan should also include a summary of the current availability of all staff assigned to the contract. This Initial Transition Plan shall also include the transfer of laboratory notebooks, equipment and property, including drug samples, chemicals and other supplies purchased with contract funds or otherwise furnished by the Government.

b. Upon receipt of written approval from the Project Officer, the Contractor shall implement the Initial Transition Plan to complete the tasks associated with transition within thirty (30) calendar days.

2. SYNTHESIZE COMPOUNDS (SMALL SCALE)

Synthesize, purify and characterize small-scale (10mg - 10g/batch) target compounds as designated by the Project Officer. The Project Officer will identify the target compounds and provide synthetic methods when available. When no synthetic route or specific procedure is provided for an assignment, the Contractor shall furnish one for the Project Officer's approval prior to starting the synthesis.

3. SYNTHESIZE COMPOUNDS (LARGE SCALE)

a. Synthesize, purify, and characterize 10 - 1000g batches of target compounds selected by the Project Officer. Prior to proceeding with scale-up synthesis, the Contractor shall provide for the Project Officer's review and approval a written synthetic method and cost estimate. Compounds shall be synthesized in large scale amounts under cGMP regulations (21 CFR Parts 210-211) unless otherwise instructed by the Project Officer.

b. The Contractor shall demonstrate compliance with safety and health regulations. The compounds targeted for synthesis should be considered toxic and shall be handled accordingly.

(1) Synthetic chemists shall routinely use fume hoods, disposable gloves, dust masks, aprons, and related protective gear. The Contractor shall provide appropriate training, protective

garments, equipment, and monitoring for all personnel involved in the handling and transport of potentially hazardous materials.

(2) The Contractor shall comply with Occupational Safety and Health Administration (OSHA) guidelines on Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR Part 1910.1450), U.S. Department of Labor regulations http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10106. Contractor shall comply with all relevant Federal, State, and local health and safety guidelines and regulations.

(3) The Contractor shall be in compliance with Environmental Protection Agency (EPA) regulations regarding the discharge of water and air pollutants and for assuring that disposal of all chemical residues meets current EPA regulations.

4. ACQUIRE COMPOUNDS FOR EFFICACY TESTING

Acquire, through purchase or donation (e.g. from a pharmaceutical company), and further characterize compounds for efficacy testing against opportunistic pathogens (*e.g., Mycobacterium tuberculosis)* associated with AIDS.

5. SHIP COMPOUNDS TO NIAID

When requested by the Project Officer, deliver assigned synthesized or acquired compounds and intermediates, under appropriate safety conditions, to the NIH AIDS Research and Reference Reagent Program at NIAID in Germantown, MD or a location designated by the Project Officer.

6. PROVIDE FACILITIES, EQUIPMENT, AND OTHER RESOURCES

Provide and maintain the following facilities, equipment and resources to carry out the requirements set forth in the Statement of Work:

a. A central facility including all necessary equipment for organic synthesis in compliance with cGMP.

b. On-site access to the following equipment: IR spectrometer, UV-VIS spectrometer, low field proton NMR, analytical high performance liquid chromatograph HPLC. On-site access is not required for high resolution mass spectroscopy and high field proton and ^{13}C NMR service capable of providing multiple irradiation data. Elemental analysis may be available in-house or from a commercial laboratory

c. Dedicated space for staff and equipment

d. Documented access to library resources including internet search capability

e. Controlled access areas for safe and secure storage of chemicals, data and confidential information.

7. FINAL TRANSITION

a. Prepare and submit, for review and written approval by the Project Officer and the Contracting Officer, a Final Transition Plan three (3) months prior to the expiration of this contract. The Final Transition Plan shall detail the transfer of all contract-related materials to a subsequent contractor or the Government.

b. Implement the Final Transition Plan as approved by the Project Officer and the Contracting Officer for the transfer of equipment and property, including drug samples, chemicals, and other supplies purchased with contract funds or otherwise furnished by the Government.

c. Provide the successor contractor with documents and electronic files necessary for the continuation of this contract including protocols detailing ongoing studies anticipated not to be completed by the expiration date.

ATTACHMENT 4
REPORTING REQUIREMENTS AND DELIVERABLES

SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES
RFP NIH-NIAID-DAIDS-08-19

A. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit technical progress reports covering the work accomplished during each reporting period.

1. Project Report

For each compound synthesized prepare a report that includes the following:

a. the synthetic process used, including scheme, all materials used and amounts, overall yield
b. analytical data sheets that include: solubility, melting point, and elemental analysis, 1H-nuclear magnetic resonance (NMR) spectra, infrared (IR) and ultraviolet-visible (UV-VIS) spectra, and when requested, mass spectroscopy (MS), and/or 13C NMR spectra
c. a Material Safety Data Sheet (MSDS) for all compounds delivered.

A Certificate of Analysis will be required for some compounds designated by the Project Officer.

2. Monthly Progress Report

This report shall include a description of the synthesis activities during the reporting period, and the activities planned for the ensuing reporting period. The Monthly progress report shall also describe any problems encountered and corrective action taken since the last monthly progress report. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month and is due on the fifteenth of the month. A Monthly Progress Report shall not be required when a Semi-Annual or Final Report is due.

3. Semi-Annual Progress Report

This report shall include a summation of previously submitted monthly reports. Monthly reports need not be submitted the month the semiannual report is due. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall

consist of six full calendar months. A Semi-Annual Progress Report shall not be required when the Final Report is due.

4. Final Report

This report shall summarize the results of the entire contract period. The Final Report shall not include detailed copies of information previously submitted in the Monthly Progress Reports or Semi-Annual Progress Reports, but shall include enough detail to document the contract's accomplishments. The Final Report shall be submitted by the expiration date of the contract.

5. Summary of Salient Results (Form 1688-1)

The Contractor shall submit, with the Final Report, a brief summary (not to exceed 200 words) of salient results achieved during the contract period of performance.

B. Technical Reports Delivery Schedule

If the Contractor is unable to deliver the reports specified above within the established due dates because of unforeseen difficulties, not withstanding 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 and a proposed revised due date. The Contracting Officer with the advice of the Project Officer will notify the Contractor regarding the appropriate action to be taken.

Item	Type of Report	Report Due	Recipients & Number of Copies
1.	Project Report	Upon delivery of synthesized compounds	1 hard copy and 1 electronic copy to PO and CO; 1 hard copy to NIAID Repository
2.	Monthly Progress Report	Monthly, due no later than 5 business days after the end of the month. Monthly Progress Report is not due when a Semi-Annual Progress or a Final Report is due.	1 hard copy and 1 electronic copy to PO and CO
3.	Semi-Annual Progress Report	Semi-annually, due no later than 15 days after the end of each 6 month period. Semi- Annual Progress Report is not due when a Final Report is due.	1 hard copy and 1 electronic copy to PO and CO

4.	Final Report	A Final Report is due on the expiration date of the contract	2 hard copies and 1 electronic copy to PO; 1 hard copy and 1 electronic copy to CO
5.	Form 1688-1	On the expiration date of the contract	1 hard and 1 electronic copy to PO and CO

C. Other Reports/Deliverables

Invention Report Requirement - **The Contractor shall inform the Government of any inventions made under the contract**

The Contractor, subject to Project Officer approval, shall deliver to the Government or its designee by the expiration date of the contract, all government-owned property.

1. Data Reports

Upon completion of this contract, all data and archived reports maintained under this contract shall be delivered to the Government and/or successor contractors, if any.

2. Initial Transition Plan

Within 30 calendar days after contract award the Contractor shall provide an Initial Transition Plan and timetable for the receipt, and storage of all items potentially being transferred from the incumbent contractor. This shall include equipment, drug samples, chemicals and other supplies purchased with contract funds or otherwise furnished by the Government.

3. Final Transition Plan

Three (3) months prior to the expiration date of the contract, the Contractor shall provide for the Project Officer's approval: (1) a Final Transition Plan, which shall include: transfer of laboratory note books, equipment and property, including drug samples, chemicals and other supplies purchased with contract funds or otherwise furnished by the Government; and (2) plans for the shipping of all government-owned property and data necessary for the continuation of this contract to the successor contractor, including a cost estimate for packing and shipping.

4. Other Reports Schedule

Item	Type of Deliverable	Report Due	Recipients & Number Copies
1.	Data Reports	By contract expiration date	1 hard and electronic copy

			each: PO and CO
2.	Initial Transition Plan (if required)	30 days after contract award	1 hard and electronic copy each: PO and CO
3.	Final Transition Plan	3 months prior to contract expiration	1 hard and electronic copy each: PO and CO

D. Copies of Reports Shall be Sent to the Following Addresses:

Project Officer
Drug Development and Clinical Sciences Branch, TRP
Division of AIDS, NIAID, NIH
Room 5149
6700-B Rockledge Drive MSC 7624
Bethesda, MD 20892-7624 (20817 for overnight deliveries)
(Email address to be provided at time of contract award)

Contracting Officer
AIDS Research Contracts Branch
Office of Acquisitions
Division of Extramural Affairs, NIAID, NIH
6700-B Rockledge Drive MSC 7612
Bethesda, MD 20892-7612 (20817 for overnight deliveries)
(Email address to be provided at time of contract award)

NIH AIDS Research and Reference Reagent Program
National Institute of Allergy and Infectious Diseases
c/o Fisher BioServices
20301 Century Blvd, Bldg. 6 Suite 200
Germantown, MD 20874

ATTACHMENT 5
ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR TECHNICAL PROPOSAL

SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES
RFP NIH-NIAID-DAIDS-08-19

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a table of contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire technical proposal is 200 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

Proposals shall NOT include links to Internet Web site addresses (URLs) or direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

I. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
II. PROJECT OBJECTIVES (NIH FORM 1688-1)
III. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
IV. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
V. TABLE OF CONTENTS
VI. MANDATORY QUALIFICATION CRITERIA

The Mandatory Qualification Criteria must be met at the time of the
☒ Initial proposal submission
☐ Final Proposal Revision submission
Section M of this solicitation includes Mandatory Qualification Criteria (MQC). Documentation to support compliance with the MQC must be provided for the prime contractor and any proposed subcontractor(s). All Offerors must provide the required supporting documentation. Include all information relevant to the MQC in this clearly marked section of your Technical Proposal, including copies of all materials necessary to demonstrate that you have met the MQC.

DOCUMENTATION REQUIRED TO SUPPORT HAVING MET THE MANDATORY QUALIFICATION CRITERIA:

All Offerors shall be registered with the United States Food and Drug Administration (FDA) as a manufacturer of bulk drugs. The facilities shall meet FDA standards in accordance with the current Good Manufacturing Practice (cGMP) guidelines. The Offeror must provide documented proof of FDA registration and most recent routine FDA inspection(s). Moreover, the Offeror must be in compliance with FDA requirements during the entire course of the contract period. The proposal must describe specific examples of products manufactured by the Offeror, which have been used in clinical trials.

Justification:

The Contractor will be asked to supply drug that is sufficiently pure, safe, and active to initiate clinical studies after FDA review. Therefore, Offeror must be able to manufacture pharmaceutical materials in compliance with current GMP regulations

SECTION 2: SCIENTIFIC AND PROFESSIONAL PERSONNEL

The Technical Proposal should include all information relevant to document education, training, accomplishments, and relevant experience of all proposed personnel, as well as the percentage of time each will be committed to the project. This includes staff of the Offeror and all proposed subcontractors and consultants. Resumes, endorsements, and explanations of previous efforts should reflect length and variety of experience in similar tasks and should clearly demonstrate specific accomplishments. Documentation should include all previous and current projects of a similar nature, including the contract number or grant number, the sponsoring agency, the Project Officer, and a description of the project. Limit CVs to three (3) pages for the Principal Investigator and two (2) pages for all other key personnel. Provide selected references for publications relevant to the scope of the RFP.

1. Principal Investigator: Describe the experience, training, expertise in chemical synthesis, and qualifications of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract. The Principal Investigator should possess at least 5 years of experience in the execution of chemical synthesis, scale-up and synthetic process development in the laboratory and pilot plant. This individual should have knowledge and experience in generating and interpreting spectroscopic data (e.g. NMR, UV-VIS, IR HPLC, and MS), and experience with the administration and overall monitoring of all technical aspects of the contract.

2. Key Scientific and Professional Personnel: Describe the experience, training, expertise and qualifications, as well as percentage of effort, for all proposed key scientific and professional personnel, including subcontractors and consultants. This includes scientific and technical expertise in organic synthesis, purification and identification of intermediates and target compounds. Knowledge

and experience in: spectroscopic and analytic techniques for characterization and analysis of purity of organic compounds

3. Describe the experience, training, and qualifications of all proposed personnel, in safety and handling of chemicals of unknown or known hazardous nature.

SECTION 3: TECHNICAL APPROACH

Technical Proposals shall describe specifically how the Offeror shall fulfill each of the items in the SOW.

1. Synthesize compounds on small (10mg - 10g/batch) and large (10 - 1000g/batch) scale and describe the synthetic process

Provide a plan/technical approach for performing synthesis, purification and characterization, on both small and large scale, of a diverse group of organic compounds. Provide three examples of recent large scale synthesis requiring diverse capability in organic synthesis accomplished by the proposed team. Describe in detail the approaches for selecting the synthetic process to be used for large scale synthesis, and methods for purification and characterization of each example. Also discuss in detail any change in the procedures you may have proposed for improving existing syntheses in preparation for scale-up syntheses. Provide a copy of a Material Safety Data Sheet (MSDS) and a certificate of analysis (COA) made by your organization for one of the synthesized compounds.

2. Synthesize compounds following cGMP regulations

Provide documentation of the Offeror's ability to synthesize compounds on a large scale in compliance with cGMP regulations.

3. Acquire, through purchase or donation, compounds for efficacy testing

Describe the approach for identifying sources for acquisition, through donation or purchase, of relevant chemical compounds of potential use as anti-HIV and/or -OI experimental therapies. Delineate the process to be used to determine the validity and authenticity of the acquired materials. These compounds should be acquired through purchase or donations through contacts with pharmaceutical and chemical companies, academic laboratories, or other sources known to the Contractor. Because of the sensitive nature of obtaining donations of compounds for testing against disease organisms, the Offeror should fully document the corporate experience and the experience of assigned staff in this type of work.

The Offeror should propose a mechanism by which this effort would be accomplished, including potential sources of such donations, proposed staff, and a proposal for maintaining confidentiality of information between the Contractor, the drug sponsor, and the Government.

4. Ship synthesized or acquired compounds to NIAID

Provide documentation of staff training and the necessary licenses to handle shipping of organic compounds of unknown or known toxicity.

5. Comply with Safety and Health Regulations

Describe how the Offeror shall comply with all pertinent local, State and Federal government safety regulations, such as those required by the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the FDA. Provide copies of relevant licenses required by local, State and Federal governments. Describe your organization's general safety program in case of fire, acid spills, explosions, etc., as well as your proposed approach for the handling of toxic agents and the protection of laboratory personnel. Describe your compliance with EPA's regulations regarding the discharge of water and air pollutants and the disposal of all chemical residues. Provide a copy of your organization's safety manual. Describe your plan for training, implementing, and monitoring safety procedures for protection of personnel and the environment from chemical and biological hazards. Include a discussion of the use of protective garments and equipment by personnel and protocols for dealing with chemical and biological spills and accidents.

SECTION 4 - FACILITIES EQUIPMENT AND OTHER RESOURCES

Describe in detail (provide floor plans) the availability of appropriate facilities including laboratory space to be used for this project. In situations where more than one building or institution is involved, a clear description shall be given of the location of all sites, distance and travel time between them. While it is expected that most of the equipment is dedicated and will be under the direct control of the Principal Investigator, special mention shall be made when this is not the case. When equipment is only available on a shared basis, evidence shall be provided as to who is responsible for controlling access and how determination of priority of usage will be made (letter of commitment from department head, etc.).

1. The Contractor should have on on-site access to the following equipment: infrared spectrometer, UV-VIS spectrometer, low field proton NMR and analytical HPLC. List available equipment, including brand names and model numbers; proximity to the project work area; and provisions for access to team members.

2. The Contractor should have available on short turnaround high resolution mass spectroscopy and high field proton and 13C NMR service capable of providing multiple irradiation data. Elemental analysis may be available in-house or from a commercial laboratory. Describe equipment or services in this category available to you, including the location of equipment, arrangements for obtaining such data in the form of a letter of commitment from the provider and the expected turnaround time.

3. Describe the library resources available to you and your internet search capability.

SECTION 5 – PROJECT MANAGEMENT

1. Overall Management

Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management and completion of all projects carried out under this contract. This infrastructure shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status, progress and costs. Describe the organization's experience in supporting synthetic organic chemistry projects. Provide a plan for project organization, staffing, and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work. Describe in detail the

responsibilities of all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants and an administrative framework (including an organization chart) indicating clear lines of authority and responsibility for all proposed personnel.

2. Meet with the Project Officer

   Meet with the Project Officer and appropriate DAIDS staff once a year for one day at NIAID offices in Bethesda, Maryland, to review progress, discuss anticipated or existing problems, and work to be performed in the near future. Additional meetings may be required, but only upon request of the Project Officer.

3. Communicate Effectively with the Project Officer

   Establish electronic communication with the Project Officer sufficient to support exchange of e-mail and the submission of data files and reports when requested. Discuss how the Principal Investigator will communicate contract progress and interact with the Project Officer and Contracting Officer to effectively monitor and manage the contract Submit Technical Reports and Other Reports/Deliverables in accordance with the Reporting Requirements and Deliverables Section of this contract.

4. Confidentiality of Information

   Describe the procedures that will be employed to safeguard the confidentiality of information provided to the Contractor by third parties or the Government, as well as data generated during the performance of the contract.

   Two documents, entitled (1) “Confidentiality of Information and Intellectual Property,” and (2) "Intellectual Property Option to be Offered to NIAID’s Third Party Providers of Proprietary Material and Protection of Resultant Proprietary Data" are included under Article B.4., Advance Understandings, of this RFP. The document entitled "Material Evaluation Agreement," is attached to this solicitation as Attachment 7. The first addresses the Contractor’s handling of confidential information and intellectual property responsibilities during the conduct of the contract. The second illustrates the type of agreement made between the DAIDS, NIAID, NIH and providers of drug substances to the Contractor for in vitro and in vivo testing. The third addresses licensing options that will be offered to providers of drug substances in the event an invention is made by the Contractor in conducting the work specified in the contract. An Advance Understanding will be written into the final contract incorporating these three documents.

SECTION 6 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

Biohazard Safety
The Technical Proposal should include a plan for biohazard safety and security requirements.

ATTACHMENT 6

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES
RFP NIH-NIAID- DAIDS-08-19

In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information provided in this appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as appendices and attachments, and the technical evaluation criteria, and, the RFP as a whole, in the development of their proposal. The information requested in these instructions shall be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET (use form NIH 2043 identified in Section J)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation shall be included in the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1. Technical Cost Assumptions

a. **Synthesize on small scale (10mg - 10g/batch) and large scale (10 - 1000g/batch) basis potential anti-infective agents.**

At the present time it is not possible to identify specific candidate compounds or the approximate ratio of small- to large scale batches. However, Offerors should anticipate that individual requests for synthesis will usually be for a compound from one of a variety of relatively simple chemical classes (*e.g.*, heterocyclic or carbocyclic), but that will require diverse capabilities in organic synthesis.

For the purpose of preparing a budget, assume the synthesis of a total of 60 known low molecular weight organic compounds per year, including 30 of 0.1g/batch, 25 of 5-10g/batch, 4 of 250g/batch, and 1 of 1000g/batch.

b. **Acquire, through purchase or donation, compounds for efficacy testing**

It is the intent of the Government that the synthesis effort, and not acquisition, will be the major emphasis of this award. For the purposes of preparing a budget, assume this acquisition task will be approximately 5% of the total effort. The acquired compounds would be for the purpose of testing for efficacy against opportunistic pathogens (*e.g., Mycobacterium tuberculosis*) associated with AIDS.

Other compounds to be acquired may include agents for which synthesis expertise or equipment may not be available at the contractor site (e.g. oligonucleotides, polypeptides, radiolabelled compounds, cytokines, etc.). These agents may be obtained by either outright purchase or through a subcontracting mechanism. It is anticipated that this mechanism will comprise a very small component of the overall award. In the event that these purchases may be required, such purchases would be expected to substitute for synthetic work normally requested of the Contractor; therefore it should not be included in the proposed cost.

2. Travel

Offerors should include a uniform assumption of one trip to Bethesda, Maryland per year, for one day, for one person.

3. Special Shipping and Packaging

Offerors should include a uniform assumption of sixty domestic chemical shipments per year.

4. Government Furnished Equipment (GFE)

Government furnished equipment (Attachment 8) will be transferred to the successful Offeror.

5. Estimated Level of Effort

Offerors shall assume an overall staffing requirement of approximately six (6) full time equivalents (FTEs) per year. This information is furnished to Offerors for information purposes only and is not to be considered restrictive for proposal purposes.

ATTACHMENT 7
DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
MATERIAL EVALUATION AGREEMENT

This Material Evaluation Agreement is made and entered into between the Division of Acquired Immunodeficiency Syndrome ("DAIDS") of the National Institute of Allergy and Infectious Diseases ("NIAID"), located at 6700B Rockledge Drive, Bethesda, Maryland 20892, and <insert company>, having its principal place of business located at <insert company's address> ("PROVIDER"). DAIDS funds a comprehensive portfolio of contracts to discover and develop novel agents for the prevention and treatment of infections caused by human immunodeficiency virus (HIV), opportunistic infections associated with AIDS, hepatitis C, and tuberculosis. PROVIDER requests to voluntarily participate in one or more of the evaluation programs (e.g., in vitro, animal model, drug development) funded by DAIDS and submits for evaluation patented or unpatented drugs, compounds, or other products ("Material") to DAIDS. Without cost to the PROVIDER, DAIDS may evaluate the submitted Material through its Contractors. DAIDS shall determine which programs shall be utilized to evaluate PROVIDER's Material and the extent of the evaluation. PROVIDER shall have the right to request limitations on the scope and extent of evaluation of the Material by DAIDS.

DAIDS and PROVIDER therefore agree as follows:

1. Definitions.

1.1 "Confidential Information" is scientific, business, or financial information the PROVIDER or DAIDS deem to be proprietary or confidential and which information is identified as "Confidential" in writing. Confidential written information shall be marked "Confidential." Oral disclosures must be reduced to writing, marked "Confidential," and sent to the other Party's Point of Contact listed in Section 11 within 10 business days after disclosure to be considered Confidential Information.

1.2 "Contractors" are DAIDS-approved non-profit and for-profit testing laboratories with contractual obligations to DAIDS.

1.3 "DAIDS" is a division within the NIAID, an institute of the National Institutes of Health ("NIH"), which is a component of the Department of Health and Human Services ("HHS"), an agency of the U.S. Government.

1.4 "Evaluations" will include the testing of the Materials in the manner described below.

a. <DAIDS to provide description of evaluations – use terms from "MEA examples list">

1.5 "Invention" means any invention or discovery which is or may be patentable or otherwise protected under Title 35, United States Code ("U.S.C."), or any novel variety or plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. §§ 2321 et seq.).

1.6 "Material" means:

a. <DAIDS & PROVIDER to negotiate Description of Material - use terms from "MEA examples list" >

1.7 "Results" means all recorded data, results, and technical information produced from the Evaluations of the Material under this Agreement and not previously disclosed by the PROVIDER.

2. Submission and Evaluations of Material.

2.1 DAIDS represents that the contracts between DAIDS and the Contractors are consistent with the terms of this Agreement.

2.2 DAIDS has the right to decline to conduct Evaluations of any Material or to limit the scope of such Evaluations. PROVIDER understands that not all Evaluations offered by DAIDS are available at all times. Evaluations must be mutually agreed to by DAIDS and PROVIDER prior to commencement of Evaluations and are delineated in Section 1.4 above. After initiation of Evaluations listed in Section 1.4, PROVIDER and/or DAIDS may request additional or advanced Evaluations. Such Evaluations are contingent upon data meeting DAIDS criteria for such Evaluations and shall be mutually agreed upon in writing and attached hereto as an Appendix.

2.3 While PROVIDER may not select the Contractors, PROVIDER has the right to decline the use of particular Contractors conducting Evaluations prior to the communication of any Material to such Contractors.

2.4 Under the direction of DAIDS, PROVIDER will forward to Contractors the Material to be tested together with a Material Safety Data sheet for each Material which contains pertinent available data as to chemical composition, purity, solubility, toxicity, and any precautions that need to be followed in handling, storing, and shipping the Material.

2.5 Material is to be used by Contractors for Evaluations under this Agreement only and for no other purpose. In addition, Material will not be chemically modified, replicated, derived or reverse engineered unless specifically necessary for the performance of the Evaluations. Such modification would require PROVIDER approval. As mutually agreed upon by the Parties, upon completion of Evaluations, all unused Material will be returned to PROVIDER or destroyed.

2.6 DAIDS will use reasonable efforts to ensure rapid ongoing communication of Results to the PROVIDER, and PROVIDER will in turn use reasonable efforts to keep DAIDS informed of PROVIDER's own concurrent studies with the Material that may affect Evaluations or Results.

3. Confidentiality.

3.1 PROVIDER may provide Confidential Information relevant to the Evaluation of the Material to DAIDS and the Contractors. DAIDS represents that the Contractors are required by their DAIDS contracts to protect such Confidential Information with reasonable efforts as specified in 3.3 below.

3.2 To the extent permitted by law, Confidential Information disclosed to DAIDS or the Contractors will remain confidential for five (5) years after the effective date of this Agreement unless the information:

a. Is known by the public or becomes known by the public through no fault of DAIDS or the Contractors;

b. Was obtained by DAIDS or the Contractors, without restriction, from a third party having no confidentiality obligation to the PROVIDER;

c. Has been independently developed by DAIDS or the Contractors without reference to the PROVIDER's Confidential information; or

d. Is required to be disclosed by law, regulation, or court order provided that PROVIDER has been notified and DAIDS or the Contractors have taken reasonable efforts to minimize the extent of the required disclosure.

3.3 No data about the Material, Evaluations, or Results will be kept in files open to the public either by DAIDS or the Contractors. Only personnel directly involved in the Evaluations will have access to the files containing Confidential Information.

3.4 PROVIDER acknowledges that Results are not Confidential Information as defined in section 1.1, and may be disclosed by DAIDS and the Contractors only in accordance with Article 4 below.

4. Disclosure of Results.

4.1 DAIDS and the Contractors may publish or otherwise publicly disclose Results after a period of six (6) months from the date of transfer of Results to PROVIDER. The six-month delay in disclosure is intended to allow PROVIDER time to file patent applications if desired.

4.2 Publication of Results earlier than the six (6) month period by DAIDS or Contractors will require PROVIDER's prior written consent, which will not be unreasonably withheld.

4.3 PROVIDER is encouraged to pursue publication of Results in conjunction with or separately from DAIDS and the Contractors. Before PROVIDER or DAIDS submit a paper or abstract for publication or otherwise intend to publicly disclose information about Evaluations or Results related to PROVIDER's Material, such as a press release, DAIDS and PROVIDER will provide the other Party fourteen (14) days to review and comment on the proposed disclosure. DAIDS will require the Contractors to consult with PROVIDER, whenever the Contractor intends to include Results in any publication or other public disclosure such as a press release.

4.4 PROVIDER will not be identified in DAIDS or Contractor publications as the source of Material without PROVIDER's prior written approval.

4.5 PROVIDER will not construe the involvement of DAIDS in Evaluations as an endorsement of Material by the U.S. Government or any of its agencies, employees, or Contractors.

4.6 PROVIDER will include acknowledgement of DAIDS/NIAID/NIH and the contract number(s) providing support in any public disclosure (e.g., publication, press release, poster at a meeting).

5. Intellectual Property.

5.1 Subject to applicable law, PROVIDER shall retain all of PROVIDER's existing intellectual property rights to Material. DAIDS acknowledges that this Agreement may not be construed as a grant by the PROVIDER of a license or any other right or interest to the Material beyond those expressly set forth herein.

5.2 PROVIDER acknowledges that the Contractors have the right to elect to retain title to any new Invention(s) made under DAIDS sponsored contracts [37 CFR 401.14(b)]. However, Contractors have agreed to an "Intellectual Property Option" as part of their contracts with DAIDS. Under the Intellectual Property Option the Contractors are required to:

a. Promptly notify DAIDS and the PROVIDER of any new Invention(s) made by the Contractors in the performance of the Evaluations under this Agreement;

b. Grant PROVIDER a paid-up, nonexclusive, nontransferable, royalty-free, world-wide license to all such new Invention(s) for research purposes only; and

c. Grant PROVIDER a time-limited first option to negotiate an exclusive, worldwide royalty-bearing license to Contractor's interest in all such new Invention(s) for all commercial purposes, including the right to grant sub-licenses, on terms to be negotiated in good faith by PROVIDER and the Contractor.

6. Warranty and Limitation of Liability.

6.1 DAIDS acknowledges and agrees that the Material is experimental in nature. **PROVIDER makes no representations and extends no warranty of any kind, either expressed or implied, including any warranty of merchantability or fitness for a particular purpose, or warranty that the use of Material will not infringe any patent, copyright, trademark, or other proprietary right.**

6.2 PROVIDER disclaims all liability for any claims, damages, or liability resulting from its activities under this agreement, unless caused by PROVIDER's gross negligence or willful misconduct. DAIDS shall be liable for any loss, claim, damage, or liability that DAIDS incurs as a result of its activities under this Agreement, except that DAIDS, as part of an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq.

6.3 No indemnification for any loss, claim, damage, or liability is intended or provided by DAIDS under this Agreement. DAIDS is prohibited under statute, the Anti-Deficiency Act 31 U.S.C. §1341, from indemnifying any party, absent other specific statutory authorization.

7. Term and Termination.

7.1 This Agreement will be in effect for five (5) years from the date of the last signature below.

7.2 DAIDS may terminate evaluations of Material based on demonstrated lack of efficacy, unanticipated toxicity, technical difficulties in performing Evaluations, lack of contract funds, or unavailability of resources. DAIDS shall notify PROVIDER in writing within five (5) business days of such a decision.

7.3 Either DAIDS or PROVIDER may terminate this Agreement at any time by giving written notice at least thirty (30) days prior to the desired termination date.

8. Amendments.

8.1 If DAIDS or PROVIDER desires an extension of, or other modification to this Agreement they will, upon reasonable notice to the other, confer in good faith to determine the desirability of the modification. No modification is effective until a written amendment is signed by authorized representatives of DAIDS and PROVIDER.

8.2 If PROVIDER desires to add Material or Evaluations not originally agreed to, prior approval from DAIDS is required and an amendment to this Agreement must be made. All terms and conditions of this Agreement will remain in full force and effect.

9. Governing Law.

The construction, validity, performance, and effect of this Agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement. The illegality or invalidity of any provisions of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

10. Survivability.

The provisions of Articles 3, 4, 5, 6, 9 and 10 will survive the termination or expiration of this Agreement.

11. Points of Contact.

For DAIDS	**For PROVIDER**
Name:	Name:
Title:	Title:
Organization:	Organization:
Street/Bldg:	Street/Bldg:
City: State: Zip:	City: State: Zip:
Phone:	Phone:
Fax:	Fax:
Email:	Email:

Accepted and agreed by the Parties through their duly authorized representatives as of the last date of signature below.

The Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)
6700B Rockledge Drive
Bethesda, MD 20892

Insert PROVIDER Name
Insert Address

Authorized Signature:

Carl W. Dieffenbach, Ph.D.
Acting Director, DAIDS, NIAID

Date: _____

Authorized Signature:

Name:

Title:

Date: _____

Intellectual Property Option to be offered to NIAID's Third Party Providers of Proprietary Material *and* Protection of Resultant Proprietary Data

This Article Must be Included In Any Subcontract for Synthesis of Material. The Subcontractor Shall Then Have All the Obligations of the Contractor.

The goal of this contract is to promote the development of critical biological information by synthesizing various materials for evaluation of their anti-microbial activity. For the purposes of this agreement, "material" includes compositions of matter, and associated information such as methods of making or using the compositions. It is expected that the great majority of materials will be proprietary to third parties. It is clear from the NIAID's experience that third party providers ("Provider") will not provide their proprietary material ("Material") without assurance that the intellectual property rights associated with their Materials will be protected. Accordingly, to encourage Providers to provide their Materials for synthesis under this contract the Contractor agrees to the Article pertaining to the Intellectual Property Option to the Provider, which requires the Contractor and its subcontractors to provide a research use license and a commercialization license option to Subject Inventions made under the contract to the Providers as follows:

The Contractor agrees to promptly notify the NIAID and the Provider in writing of any Subject Inventions of the Contractor, its principal investigator and/or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of work under this contract using a Provider's Material (hereinafter "Contractor Invention"). The notice shall inform the Provider(s) of its right to the option set forth herein. This may be accomplished by attaching a copy of the Article to the notice.

(1) Single Provider

With respect to Contractor Inventions resulting from the use of Material provided by one Provider, the Contractor agrees to grant to the Provider: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to any Contractor Invention on terms to be negotiated in good faith by the Provider and the Contractor, subject to the following conditions:

The Contractor will allow Provider three (3) months from the date the Contractor sends written notice to the Provider of the existence of a Contractor Invention (or such additional period as the Provider and the Contractor may agree) to notify the Contractor in writing, whether or not it wants to obtain an exclusive license to the Contractor Invention. If the Provider fails to notify the Contractor, in a timely fashion then the Contractor's obligation to offer Provider a license option with respect to that Contractor Invention will expire, and the Contractor will be free to dispose of its interests in such Contractor Invention in accordance with the Contractor's policies. If the Contractor and the Provider fail to reach agreement within ninety (90)

days, (or such additional period as the Provider and the Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter the Contractor will not offer to license that Contractor Invention to any third party on materially better terms than those last offered to the Provider without first offering such terms to the Provider, in which case the Contractor will offer the Provider a period of thirty (30) days in which the Provider can accept or reject the offer.

(2) Multiple Providers

With respect to a Contractor Invention resulting from the use of Materials provided by multiple Providers, but which is an improvement only to a Material of a specific Provider, the Contractor agrees to grant to that Provider the rights described above in (1).

With respect to any Contractor Inventions resulting from the use of Material from multiple Providers, but that are not improvements to or specific to a single Material, the Contractor agrees to grant to each Provider who provided Material: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate a co-exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all such Contractor Inventions on terms to be negotiated in good faith by each Provider and the Contractor subject to the following conditions:

The Contractor will allow each Provider three (3) months from the time the Provider is sent written notice by the Contractor of the existence of a Contractor Invention (or such additional period as each Provider and the Contractor may agree) to notify the Contractor, in writing, whether or not the Provider wants to obtain a co-exclusive license to the Contractor Invention. If a Provider fails to notify the Contractor, in a timely fashion then Contractor's obligation to offer that Provider a license option with respect to that Contractor Invention will expire and the Contractor will continue to offer an option to a co-exclusive license to the other Providers as set forth herein. If there is a single other Provider, it shall be offered an option to an exclusive license as though it were a single Provider. If no Provider notifies the Contractor in a timely fashion the Contractor will be free to dispose of its interests in such Contractor Invention in accordance with the Contractor's policies.

Provider Inventions

The Contractor agrees that notwithstanding anything herein to the contrary, any invention or discovery, whether patentable or not, which is not a Subject Invention as defined in **35 USC 201(e)**[1] but arises out of an intentional and unauthorized use or modification of the Provider's Material by the Contractor and/or any other employees or agents of the Contractor, will be the property of the Provider (hereinafter "Provider Invention"). The Contractor will promptly notify the Provider in writing of any such Provider Inventions and, at the Provider's request and expense, the Contractor will cause to be assigned to the Provider all right, title and interest in and to any such Provider Inventions and give Provider any assistance reasonably necessary to obtain patents (including causing the execution of any invention assignment or other documents). The NIAID recognizes that the Contractor may also be conducting other research using the Provider's Material under the authority of a separate agreement with the Provider during the term of this contract; any invention arising under such separate agreement will not be subject to the terms of this provision entitled, **"Provider Inventions."**

Protection of Proprietary Data

All Materials, data and other information supplied by the Provider or the Project Officer shall be assumed to be confidential unless specifically identified as not confidential in writing by the Project Officer. The Contractor agrees that its principal investigator and/or any other employees or agents of the Contractor will provide the data generated under this contract exclusively to the NIAID or if directed by the NIAID, to the Provider and the FDA or other appropriate Federal agency. The Contractor understands that the NIAID must negotiate individual agreements with the various Providers to obtain Materials and that the terms of the agreements may vary. The NIAID intends that these agreements will provide for the Contractor's right to publish results generated by the Contractor under this contract after a reasonable period of time to allow the Provider to file patent applications and to protect its proprietary information. The Contractor agrees to enter into confidentiality agreements with Providers when required by the Providers as a condition for the Contractor to receive Materials. Such agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the Provider to obtain Materials. In the event the Contractor reasonably objects to the terms of the confidentiality agreement, the Contractor shall promptly bring such objection to the attention of the Contracting Officer for an appropriate resolution.

[1]35 USC 201(e): The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

ATTACHMENT 8

GOVERNMENT FURNISHED EQUIPMENT

SYNTHESIS OF THERAPEUTIC AGENTS FOR TREATMENT OF INFECTIOUS DISEASES
RFP NIH-NIAID-DAIDS-08-19

The following equipment will be provided to the Offeror upon contract award:

DESCRIPTION	MODEL#	MANUFACTURER
LIQUID CHROMATOGRAPHY SYSTEM:	1100 LC	
QUATERNARY PUMP	G1311A	AGILENT
DEGASSER	G1379A	AGILENT
AUTOSAMPLER	G1313A	AGILENT
DIODE ARRAY DETECTOR	G1315B	AGILENT
COMPUTER, CPU WITH SOFTWARE	d530	AGILENT
PRINTER	LJ2300d	AGILENT
DISPLAY, LCD	HP 1702	AGILENT
COLUMN COMPARTMENT	G1316A	HEWLETT PACKARD