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

## **RFP-NIH-NIAID-DMID-07-11**

## "Network on Antimicrobial Resistance in Staphylococcus aureus (NARSA)"

				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. <u>http://www.fedbizopps.gov/</u>				
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:4. Due Dat	Issue Date: 4. Due Date: May 8, 2006			<ul> <li>5. Small Bus. Set-Aside: []Yes [X] No</li> <li>8(a) Set-Aside: []Yes [X] No</li> <li>NAICS #: 541710</li> <li>(See Part IV, Section L.)</li> </ul>
6. <b>Just In Time:</b> 7	7. Number of Awa	ards:		8. Technical Proposal Page Limits:
[X] No [ ] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards			See Section J, Attachment 1, Packaging and Delivery of Proposal
• I ID	1			
9. Issued By:	10. [X] <b>NIAID</b>	reserves th	e righ	t to make awards without discussion.
Barbara A. Shadrick	11. Options:		12. <b>P</b>	Period of Performance: 7 years
Contracting Officer	-			
Office of Acquisitions, DEA, NIH, NIAID	[X] No		Febru	ary 16, 2007 through February 15, 2014
6700-B Rockledge Drive	[] Yes (See			
Room 3214, MSC 7612 Bethesda, MD 20892-7612	Sect	ion L.)		
	4. Secondary Poir	t of Conta	ot.	15. Protest Officer:
	Name: Barbara A			15. Houst Oncer.
	<b>Phone:</b> 301-496-72			Program Director, OA
Fax: 301-402-0972	<b>Fax:</b> 301-402-0972			Address (see Block 9.)
16. COLLECT CALLS WILL NOT BE A	ACCEPTED. FAC	SIMILE S	UBMI	SSIONS ARE NOT ACCEPTABLE.
17. Offers will be valid for 120 days unless				
Summary and Data Record, NIH-2043"	(See Part III, SECT	ION J – Att	tachme	nts)
18. DELIVERY ADDRESS INFORMATION				
19. Hand Delivery or Overnight Service:				Service or an Express Delivery Service
Dominic Reeves			Dominic Reeves	
		Contract Specialist		
Office of Acquisitions Of		Office of Acquisitions		
		DEA, NIAID, NIH		
6700-B Rockledge Drive, Room 3214, MSC 76126700-B Rockledge Drive, RoomBethesda, MD 20817-7612Bethesda, 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 05-07 (01/03/2006)

#### DETAILED TABLE OF RFP CONTENTS

#### PART I - THE SCHEDULE

SECTION A - SOLICITATION/CONTRACT FORM SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS	<u>5</u>
SECTION D - PACKAGING, MARKING AND SHIPPING	
SECTION E - INSPECTION AND ACCEPTANCE	
SECTION F - DELIVERIES OR PERFORMANCE	
SECTION G - CONTRACT ADMINISTRATION DATA	
SECTION H - SPECIAL CONTRACT REQUIREMENTS	
PART II - CONTRACT CLAUSES	. 23
SECTION I - CONTRACT CLAUSES	. 23
ARTICLE I.1. GENERAL CLAUSE LISTING(S)	. 23
ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES	. 23
ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES	. 24
ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT	. 25
PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	. <u>33</u>
SECTION J - LIST OF ATTACHMENTS	. <u>33</u>
PART IV - REPRESENTATIONS AND INSTRUCTIONS	. <u>35</u>
SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF	
OFFERORS	. <u>35</u>
SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS	
1. GENERAL INFORMATION	
a. INSTRUCTIONS TO OFFERORSCOMPETITIVE ACQUISITION	
b. NAICS CODE AND SIZE STANDARD	<u>39</u>
c. TYPE OF CONTRACT AND NUMBER OF AWARD(S)	. <u>40</u>
d. ESTIMATE OF EFFORT	. <u>40</u>
e. COMMITMENT OF PUBLIC FUNDS	
f. COMMUNICATIONS PRIOR TO CONTRACT AWARD	
g. RELEASE OF INFORMATION	
h. COMPARATIVE IMPORTANCE OF PROPOSALS	
i. PREPARATION COSTS	
j. SERVICE OF PROTEST	
k. LATE PROPOSALS AND REVISIONS	<u>41</u>
2. INSTRUCTIONS TO OFFERORS	
a. GENERAL INSTRUCTIONS	
(1) Contract Type and General Clauses	
(2) Authorized Official and Submission of Proposal	
(3) Proposal Summary and Data Record (NIH-2043)	
(4) Separation of Technical and Business Proposals	
(5) Alternate Proposals	. <u>43</u>
(6) Evaluation of Proposals	. <u>43</u>
(7) Potential Award Without Discussions	
(8) Use of the Metric System of Measurement	
(9) Standards for Privacy of Individually Identifiable Health Information	
(10) Privacy Act - Treatment of Proposal Information	
(11) Obtaining and Disseminating Biomedical Research Resources	
(12) Electronic and Information Technology Accessibility	
(13) Institutional Responsibility Regarding Conflicting Interests of Investigators	
(14) ROTC Access and Federal Military Recruiting on Campus	. <u>47</u>
(15) Past Performance Information	. <u>47</u>
(16) Solicitation Provisions Incorporated by Reference	. <u>48</u>

	ECHNICAL PROPOSAL INSTRUCTIONS       49         ) Technical Discussions       49         2) Technical Evaluation       51         3) Additional Technical Proposal Information       51         4) Other Considerations       51         5) Information Technology Systems Security       51
	USINESS PROPOSAL INSTRUCTIONS       55         ) Basic Cost/Price Information       55         2) Proposal Cover Sheet       55         3) Information Other than Cost or Pricing Data       55
	Requirements for Cost or Pricing Data or Information Other than Cost and Pricing
	Data
	5) Salary Rate Limitation in Fiscal Year 2006
	<ul> <li>Small Business Subcontracting Plan</li></ul>
	<ul> <li>HUBZone Small Business Concerns</li></ul>
	9) Qualifications of the Offeror
	0) Other Administrative Data
	1) Subcontractors
	2) Proposer's Annual Financial Report
	3) Representations and Certifications
	4) Travel Costs/Travel Policy
SECTION M - E	ALUATION FACTORS FOR AWARD
1. GENI	—
2. EVAL	IATION OF DATA SHARING PLAN $\ldots$ $\overline{65}$
	NICAL EVALUATION CRITERIA $\dots$ $\overline{65}$
	PERFORMANCE FACTOR
5. EXTE	IT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION $\dots \dots \dots$
	TTACHMENTS INCLUDED WITH THE RFP

## 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 PROPOSED CONTRACT DOCUMENT. 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. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR 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 solicitation is to recompete the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) to strengthen research on antibiotic resistance in *S. aureus* by facilitating communications within the research community and providing research resources to multi-disciplinary investigators and clinicians studying and treating antibiotic resistant *S. aureus*. These resources are intended to address the public health problems the nation is facing with antibiotic resistance by fostering communication and facilitating research into mechanisms of antibiotic resistance. Under the contract to be awarded through this solicitation, current NARSA activities will be continued with some activities redefined to ensure flexibility.

#### **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 <u>any</u> 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.

#### 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 January 23, 2006, attached hereto and made a part of this Solicitation. [See Attachment 4]

#### **ARTICLE C.2. REPORTING REQUIREMENTS**

**b.** Reporting Requirements and Deliverables

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. [See Attachment 5, "Reporting Requirements and Deliverables"]

## **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 identified in Article G.1., is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at the NIAID, DMID, BMB, 6610 Rockledge Drive, Bethesda, MD 20892.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

**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 52.246-8, Inspection of Research and Development - Cost-Reimbursement (May 2001).

#### **SECTION F - DELIVERIES OR PERFORMANCE**

#### **ARTICLE F.1. DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items in SECTION C, ARTICLE C.2. in accordance with the stated delivery schedule.

**a.** The items described in <u>SECTION C</u>, <u>ARTICLE C.2</u>. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the dates specified in SECTION C, ARTICLE C.2. and any specification stated in <u>SECTION D</u>, <u>PACKAGING</u>, <u>MARKING AND SHIPPING</u>, of the contract.

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

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. Also, the full text of a clause may be accessed electronically at this address: <u>http://www.arnet.gov/far/</u>.

#### 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**

Any contract awarded from this RFP will contain the following:

#### 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 any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

#### ARTICLE G.2. KEY PERSONNEL

The personnel specified in this contract are considered to be essential to the work to be performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this article. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

The following individuals are considered to be essential to the work being performed hereunder:

NAME TITLE [To be specified prior to award]

[NOTE: Below are Articles for invoice submission and financial reporting. The appropriate Articles will be selected and placed in any resultant contract based upon the type of organization that receives an award.]

#### 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 instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.
  - (1) Invoices/financing requests shall be submitted as follows:
    - (a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e.HHSN266200711000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-71000.)

(b) An original and two copies to the following designated billing office:

Contracting Officer National Institutes of Health, NIAID DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

- (2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-0612.
- **b.** The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the applicable Public Law Number for the applicable Fiscal Year as stated in SECTION H, of the above referenced contract."

- OR -

# ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

**a.** Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

- (1) Invoices/financing requests shall be submitted as follows:
  - (a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200711000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-71000.)

(b) An original and two copies to the following designated billing office:

Contracting Officer National Institutes of Health, NIAID DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

- (2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-0612.
- **b.** The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the applicable Public Law Number for the applicable Fiscal Year as stated in SECTION H, of the above referenced contract."

- OR -

#### ARTICLE G.3. LETTER OF CREDIT PAYMENT INFORMATION [only for offerors with approved letter of credit]

a. Advance payments will be provided under Letter of Credit Number \_\_\_\_\_\_ in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, <u>http://www.access.gpo.gov/nara/cfr/waisidx\_00/31cfr205\_00.html</u>).

(1) Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

An original and two copies to the following office:

Contracting Officer National Institutes of Health, NIAID DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3214, MSC 7612 Behtesda, MD 20892-7612

(2) Inquiries regarding payments should be directed to the following office administering advance payments:

Division of Payment Management 11400 Rockville Pike Rockwall Building #1, Suite 700 Rockville, MD 20852 (http://www.dpm.psc.gov/ under Contacts) b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the applicable Public Law Number for the applicable Fiscal Year as stated in SECTION H, of the above referenced contract."

#### **ARTICLE G.4. CONTRACT FINANCIAL REPORT**

- a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.
- b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "PREPARATION INSTRUCTIONS," all columns A through J, shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the effective date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

Percentage of Effort/Hours

e. The following is a listing of expenditure categories to be reported:

Expenditure Category	
А	

- (1) Direct Labor
  - (a) Principal Investigator
  - (b) Co-Principal Investigator
  - (c) Key Personnel
    - (i)
    - (ii)
    - (iii)
- (2) Other Professional Personnel
- (3) Personnel Other
- (4) Fringe Benefits
- (5) Accountable Personal Property
- (6) Materials/Supplies
- (7) Patient Care Costs
- (8) Travel
- (9) Consultant Costs
- (10) Premium Pay
- (11) Computer Costs
- (12) Subcontract Costs
- (13) Other Direct Costs
- (14) Indirect Costs
- (15) G&A Expense
- (16) Total Cost
- (17) Fee

#### (18) Total Cost Plus Fixed Fee

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

#### ARTICLE G.5. INDIRECT COST RATES [applicable to commercial contractors]

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 Contracts Management National Institutes of Health 6100 Building, Room 6B05 6100 Executive Boulevard, MSC 7540 Bethesda, MD 20892-7540

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

#### ARTICLE G.6. 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 DHHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990) which can be found at:

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

#### ARTICLE G.7. 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 evaluations may be prepared following Year 1 and every other year thereafter (or more frequently as determined by the Contracting Officer) to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted 30 calendar 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. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

#### ARTICLE H.3. 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 46.208(a)(2) 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]

#### (NOTE: For FY-06 Public Law and Section No. are P.L. 109-149, Title V-General Provisions, Section 509)

#### ARTICLE H.4. 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]

#### (NOTE: For FY-06 Public Law and Section No. are P.L. 109-149, Title V-General Provisions, Section 509)

#### ARTICLE H.5. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document may be accessed at: <u>http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm</u>

#### ARTICLE H.6. SUBCONTRACTING PROVISIONS

#### a. Small Business Subcontracting Plan

- (1) The Small Business Subcontracting Plan, dated \_\_\_\_\_\_ is attached hereto and made a part of this contract.
- (2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

#### b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at <u>http://www.esrs.gov</u>.

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30<sup>th</sup>

For both the Individual and Summary Subcontract Reports, the Contracting Specialist shall be included as a contact for notification purposes at the following e-mail address:

#### dreeves@niaid.nih.gov

Dominic Reeves Contract Specialist

#### **ARTICLE H.7. 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 per year 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 No. Fiscal Year

Dollar Amount of Salary Limitation\*

[Applicable information to be included at award]

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

For the period 10/1/05 - 12/31/05, the Executive Level I rate is \$180,100. Effective January 1, 2006, the Executive Level I rate increased to \$183,500 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

#### FOR FY-06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:

http://www.opm.gov/oca/06tables/html/ex.asp

(Note: This site shows the FY-06 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates.)

#### **ARTICLE H.8. INFORMATION SECURITY**

The Statement of Work (SOW) requires the contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the "DHHS Information Security Program Policy" (<u>http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc</u>) as set forth below. The contractor shall include this provision in any subcontract awarded under this contract.

#### a. Information Type

- \*\*\*\* (NOTE: The resultant contract will include the Information Type, however for the purposes of this RFP, the Information Type is specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) \*\*\*\*
- [] Administrative, Management and Support Information:
- [] Mission Based Information:
- b. Security Categories and Levels
  - \*\*\*\* (NOTE: The resultant contract will include the Security Categories and Levels, however for the purposes of this RFP, the Security Categories and Levels are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) \*\*\*\*

Overall	Level:	[ ] Low	[] Moderate	[] High
Confidentiality	Level:	[ ] Low	[ ] Moderate	[ ] High
Integrity	Level:	[ ] Low	[ ] Moderate	[ ] High
Availability	Level:	[ ] Low	[ ] Moderate	[ ] High

- c. <u>Position Sensitivity Designations</u>
  - (1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract:
    - \*\*\*\* (NOTE: The resultant contract will include the Position Sensitivity Designations, however for the purposes of this RFP, the Position Sensitivity Designations applicable to this RFP are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) \*\*\*\*
    - [] Level 6: Public Trust High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).
    - [] Level 5: Public Trust Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
    - [] Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

(2) The contractor shall submit a roster, by name, position and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (15) calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at:

http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government's notification of applicable Suitability Investigation required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <u>http://ais.nci.nih.gov</u>.

Contractor employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

(3) Contractor employees shall comply with the DHHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor employees may begin work under the contract after the contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c.(2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the preappointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor employee to work under the contract.

d. Systems Security Plan

The contractor shall protect Federal automated information systems that are developed or accessed by the contractor. System security shall be accomplished in accordance with the contractor's System Security Plan dated \_\_\_\_\_\_. The plan must:]

(1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The contractor shall use the NIH Systems Security Plan Template (detailed) at <u>http://irm.cit.nih.gov/security/secplantemp.doc</u> or NIH Systems Security Plan Outline (outline only) at <a href="http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc">http://irm.cit.nih.gov/security/secplantemp.doc</a> or NIH Systems Security Plan Outline (outline only) at <a href="http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc">http://irm.cit.nih.gov/security/secplantemp.doc</a> or NIH Systems Security Plan Outline (outline only) at <a href="http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc">http://irm.cit.nih.gov/security/secplantemp.doc</a> or NIH Systems Security Plan Outline (outline only) at <a href="http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc">http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc</a>.

#### [OR (To be determined during negotiations)]

- (1) Include a plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:
  - (i) Security Awareness Training
  - Logical Access Control

     Network (ex: firewall)
     System (ex: network OS, tcp wrappers, SSH)
     Application (ex: S-LDAP, SSL)
     Remote Access (ex: VPN)
     Monitoring and support (ex: IDS, pager, NOC)

- (iii) Protection against data loss
  - -OS security (ex: patch management, configuration)
  - -Application security (ex: patch management)
  - -Database security
  - -Back-up and recovery
  - -Fault tolerance, high availability
- (iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
- (v) Physical Security
  - -Access control (ex: locks, guards) -Power conditioning and/or UPS -Air conditioning
  - -Fire protection

Include an acknowledgment of its understanding of the security requirements.

Provide similar information for any proposed subcontractor developing or accessing an AIS.

e. Rules of Behavior

The contractor shall comply with the the **NIH Information Technology General Rules of Behavior** at: <u>http://irm.cit.nih.gov/security/nihitrob.html</u>.

#### f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (<u>http://irtsectraining.nih.gov/</u>) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

Contractor staff shall complete the following additional training prior to performing any work under this contract:

#### \*\*\*\* [Additional courses will be listed here in the resultant contract, if applicable.] \*\*\*\*

#### g. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

#### h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive Department information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

-18 U.S.C. 641 (Criminal Code: Public Money, Property or Records) -18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information) -Public Law 96-511 (Paperwork Reduction Act) (2) Contractor-Employee Non-Disclosure Agreements

Each contractor employee who may have access to sensitive Department information under this contract shall complete Commitment To Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

- i. <u>References</u>
  - 1. DHHS Information Security Program Policy: <u>http://www.hhs.gov/ohr/manual/pssh.pdf</u>
  - 2. DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
  - 3. NIST Special Publication 800-16, Information Technology Security Training Requirements: <u>http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf</u>
    - Appendix A-D: http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
  - 4. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
  - 5. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: <u>http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf</u>
  - 6. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: <u>http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60/2-final.pdf</u>
  - 7. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf
  - 8. NIH Computer Security Awareness Training Course: <u>http://irtsectraining.nih.gov/</u>
  - 9. Roster of Employees Requiring Suitability Investigations: <u>http://ais.nci.nih.gov/forms/Suitability-roster.xls</u>
  - 10. NCI Information Technology Security Policies, Background Investigation Process: http://ais.nci.nih.gov/
  - NIH Systems Security Plan Template (detailed): <u>http://irm.cit.nih.gov/security/secplantemp.doc</u>
     NIH Systems Security Plan Outline (outline only):
  - <u>http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc</u>
     NIH Information Technology General Rules of Behavior: http://irm.cit.nih.gov/security/nihitrob.html
  - 14. Commitment To Protect Non-Public Information Contractor Agreement: http://irm.cit.nih.gov/security/Nondisclosure.pdf

#### ARTICLE H.9. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at <a href="http://www.access-board.gov/">http://www.access-board.gov/</a>.

#### **ARTICLE H.10. 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 <u>http://www.energystar.gov/</u> For more information about FEMP see <u>http://www.eere.energy.gov/</u>

#### ARTICLE H.11. PUBLICATION AND PUBLICITY

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 Disease, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN266200711000C."

#### ARTICLE H.12. 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]

#### (NOTE: For FY-06 Public Law and Section No. are P.L. 109-149, Title V-General Provisions, Section 506)

#### ARTICLE H.13. 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.14. 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]

(NOTE: For FY-06 Public Law and Section No. are P.L. 109-149, Title V-General Provisions, Section 503a (for subparagraph a., above) and Section 503B (for subparagraphb., above).)

#### ARTICLE H.15. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology

#### YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

#### 2. Noncommercial Supply Items Warranty

#### YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

#### YEAR 2000 COMPLIANT ITEMS

All hardware and software used to manipulate date under the contract,

(End of Clause)

3. Commercial Supply Products Warranty

#### YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the product documentation provided by the contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the contractor's standard commercial warranty or warranties contained in this

contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

#### YEAR 2000 COMPLIANT ITEMS

All hardware and software used to manipulate date under the contract, (End of Clause)

#### ARTICLE H.16. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: <u>http://ott.od.nih.gov/NewPages/64FR72090.pdf</u>, is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

#### ARTICLE H.17. SHARING RESEARCH DATA

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

#### http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at <a href="http://www.hhs.gov/ocr/">http://www.hhs.gov/ocr/</a>). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

#### ARTICLE H.18. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <u>http://www.usfa.fema.gov/hotel/index.htm</u>

# ARTICLE H.19. 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 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

#### **ARTICLE H.20. CONSTITUTION DAY**

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

## 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

General Clauses for a Cost-Reimbursement Contract with Educational Institutions

General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

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

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 Clause **52.216-7**, **Allowable Cost And Payment** (December 2002), is modified in paragraph (a). The reference to Subpart 31.2 is changed to Subpart 31.3.

Alternate I of FAR Clause 52.216-11, Cost Contract--No Fee (April 1984), is added.

Alternate II (October 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (July 2005) is added.

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.]* 

#### **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 **52.204-9**, Personal Identity Verification of Contractor Personnel (January 2006).
- (2) FAR Clause 52.216-15, Predetermined Indirect Cost Rates (April 1998).
- (3) FAR Clause **52.219-4**, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (July2005).
  - "(c) Waiver of evaluation preference.....
    - [ ] Offeror elects to waive the evaluation preference."
- (4) FAR Clause **52.219-25**, **Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (October 1999)**.
- (5) FAR Clause **52.223-3**, Hazardous Material Identification and Material Safety Data (January 1997), with Alternate I (July 1995).
- (6) FAR Clause 52.223-12, Refrigeration Equipment and Air Conditioners (May 1995).
- (7) FAR Clause **52.224-1**, **Privacy Act Notification** (April 1984).
- (8) FAR Clause 52.224-2, Privacy Act (April 1984).
- (9) FAR Clause 52.227-14, Rights in Data General (June 1987).
- (10) Alternate III (June 1987), FAR Clause 52.227-14, Rights in Data--General (June 1987).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows:

[to be determined during negotiations]

(11) Alternate V (June 1987), FAR Clause 52.227-14, Rights in Data--General (June 1987).

Specific data items that are not subject to paragraph (j) include: None.

- (12) FAR Clause **52-227-15**, Representation of Limited Rights Data and Restricted Software (May 1999).
- (13) FAR Clause 52.227-16, Additional Data Requirements (June 1987).
- (14) FAR Clause **52.230-2**, Cost Accounting Standards (April 1998).
- (15) FAR Clause 52.230-3, Disclosure and Consistency of Cost Accounting Practices (April 1998).
- (16) FAR Clause **52.230-5, Cost Accounting Standards Educational Institution** (April 1998).
- (17) FAR Clause 52.230-6, Administration of Cost Accounting Standards (April 2005).

- (18) FAR Clause **52.239-1**, **Privacy or Security Safeguards** (August 1996).
- (19) FAR Clause **52.242-3**, **Penalties for Unallowable Costs** (May 2001).
- (20) FAR Clause 52.243-2, Changes--Cost Reimbursement (August 1987), Alternate V (April 1984).
- (21) FAR Clause 52.247-63, Preference for U.S. Flag Air Carriers (June 2003).

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

- (1) HHSAR Clause **352.223-70**, **Safety and Health** (January 2001). [This clause is provided in full text in Section J Attachments.]
- (2) HHSAR Clause **352.270-1**, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (January 2001).

#### 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 52.204-9, Personal Identity Verification of Contractor Personnel (January 2006)

- (a) The Contractor shall comply with agency personal identity verification procedures identified in the contract that implement Homeland Security Presidential Directive-12 (HSPD-12), Office of Management and Budget (OMB) guidance M-05-24, and Federal Information Processing Standards Publication (FIPS PUB) Number 201.
- (b) The Contractor shall insert this clause in all subcontracts when the subcontractor is required to have physical access to a federally-controlled facility or access to a Federal Information system.

#### b. <u>FAR Clause 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees</u> (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--
  - 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.

#### c. FAR Clause 52.223-11, Ozone-Depleting Substances (May 2001)

- (a) **Definition.** Ozone-depleting substance, as used in this clause, means any substance the Environmental Protection Agency designates in 40 CFR part 82 as--
  - (1) Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or
  - (2) Class II, including, but not limited to, hydrochlorofluorocarbons.
- (b) The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), and (d) and 40 CRF Part 82, Subpart E as follows:

"WARNING: Contains (or manufactured with, if applicable) \_\_\_\_\_\*, a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere."

\*The Contractor shall insert the name of the substance(s).

#### d. <u>Alternate V, Advance Payment Without Special Account (May 2001) and Alternate IV (April 1984), of</u> FAR Clause 52.232-12, Advance Payments (May 2001).

- (a) Requirements for payment. Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the contractor, and approval by the administering office, [insert the name of the office designated under agency procedures], or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed \$ \_\_\_\_\_. If a letter of credit is used, the Contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The Contractor shall apply terms similar to this clause to any advance payments to subcontractors.
- (b) Use of funds. The Contractor may use advance payment funds only to pay for properly allocable, allowable, and reasonable costs for direct materials, direct labor, and indirect costs. Determinations of whether costs are properly allocable, allowable, and reasonable shall be in accordance with generally accepted accounting principles, subject to any applicable subparts of Part 31 of the Federal Acquisition Regulation.
- (c) Repayment to the Government. At any time, the Contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the Contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the Contractor's current requirements or the amount specified in paragraph (a) of this clause.
- \*\*\*\* (NOTE: The following paragraph (d) applies to Cost-Reimbursement contracts as prescribed in Alternate II of FAR 52.232-12) \*\*\*\*
- Maximum payment. When the sum of all unliquidated advance payments, unpaid interest charges, and (d) (not including fixed-fee, if any) for the work other payments equal the total estimated cost of \$ under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and interest charges payable. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed \$ [Insert an amount not higher than 10 percent of the stated estimated cost inserted in this paragraph. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.

## \*\*\*\* (NOTE: The following paragraph (e) applies to Cost-Reimbursement contracts as prescribed in Alternate II and IV of FAR 52.232-12.) \*\*\*\*

(e) *Interest.* No interest shall be charged to the prime Contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.

- (1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate specified in subparagraph (e)(3) below. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge, the following shall be observed:
  - (i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check.
  - (ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer.
  - (iii) Liquidations by deductions from payments to the Contractor shall be considered as decreasing the unliquidated balance as of the dates on which the Contractor presents to the Contracting Officer full and accurate data for the preparation of each voucher. Credits resulting from these deductions shall be made upon the approval of the reimbursement vouchers by the Disbursing Officer, based upon the Contracting Officer's certification of the applicable dates.
- (2) Interest charges resulting from the monthly computation shall be deducted from any payments on account of the fixed-fee due to the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments of the contract price or fixed-fee. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon (i) satisfactory completion or (ii) termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors for experimental, developmental, or research work.
- (3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.
- (4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.
- (f) Lien on property under contract. (1) All advance payments under this contract, together with interest charges, shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, on the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the Contractor.
  - (2) The Contractor shall identify, by marking or segregation, all property that is subject to a lien in favor of the Government by virtue of any terms of this contract in such a way as to indicate that it is subject to a lien and that it has been acquired for or allocated to performing this contract. If, for any reason, the supplies, materials, or other property are not identified by marking or segregation, the Government shall be considered to have a lien to the extent of the Government's interest under this contract on any mass of property with which the supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over the property on its books and records.

- (3) If, at any time during the progress of the work on the contract, it becomes necessary to deliver to a third person any items or materials on which the Government has a lien, the Contractor shall notify the third person of the lien and shall obtain from the third person a receipt in duplicate acknowledging the existence of the lien. The Contractor shall provide a copy of each receipt to the Contracting Officer.
- (4) If, under the termination clause, the Contracting Officer authorizes the contractor to sell or retain termination inventory, the approval shall constitute a release of the Government's lien to the extent that--
  - (i) The termination inventory is sold or retained; and
  - (ii) The sale proceeds or retention credits are applied to reduce any outstanding advance payments.
- (g) Insurance. (1) The Contractor shall maintain with responsible insurance carriers--
  - Insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality;
  - (ii) Adequate insurance against liability on account of damage to persons or property; and
  - (iii) Adequate insurance under all applicable workers' compensation laws.
  - (2) Until work under this contract has been completed and all advance payments made under the contract have been liquidated, the Contractor shall--
    - (i) Maintain this insurance;
    - Maintain adequate insurance on any materials, parts, assemblies, subassemblies, supplies, equipment, and other property acquired for or allocable to this contract and subject to the Government lien under paragraph (f) of this clause; and
    - (iii) Furnish any evidence with respect to its insurance that the administering office may require.
- (h) *Default*. (1) If any of the following events occur, the Government may, by written notice to the Contractor, withhold further payments on this contract:
  - (i) Termination of this contract for a fault of the Contractor.
  - (ii) A finding by the administering office that the Contractor has failed to--
    - (A) Observe any of the conditions of the advance payment terms;
    - (B) Comply with any material term of this contract;
    - (C) Make progress or maintain a financial condition adequate for performance of this contract;
    - (D) Limit inventory allocated to this contract to reasonable requirements; or
    - (E) Avoid delinquency in payment of taxes or of the costs of performing this contract in the ordinary course of business.
  - (iii) The appointment of a trustee, receiver, or liquidator for all or a substantial part of the Contractor's property, or the institution of proceedings by or against the Contractor for bankruptcy, reorganization, arrangement, or liquidation.
  - (iv) The commission of an act of bankruptcy.
  - (2) If any of the events described in subparagraph (h)(1) of this clause continue for 30 days after the written notice to the Contractor, the Government may take any of the following additional actions:
    - (i) Charge interest, in the manner prescribed in paragraph (e) of this clause, on outstanding advance payments during the period of any event described in subparagraph (h)(1) of this clause.
    - (ii) Demand immediate repayment by the Contractor of the unliquidated balance of advance payments.

- (iii) Take possession of and, with or without advertisement, sell at public or private sale all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to the sale, apply the net proceeds of the sale to reduce the unliquidated balance of advance payments or other Government claims against the Contractor.
- (3) The Government may take any of the actions described in subparagraphs (h)(1) and (h)(2) of this clause it considers appropriate at its discretion and without limiting any other rights of the Government.
- (i) *Prohibition against assignment*. Notwithstanding any other terms of this contract, the Contractor shall not assign this contract, any interest therein, or any claim under the contract to any party.
- (j) Information and access to records. The Contractor shall furnish to the administering office (1) monthly or at other intervals as required, signed or certified balance sheets and profit and loss statements, and, (2) if requested, other information concerning the operation of the contractor's business. The Contractor shall provide the authorized Government representatives proper facilities for inspection of the Contractor's books, records, and accounts.
- (k) Other security. The terms of this contract are considered to provide adequate security to the Government for advance payments; however, if the administering office considers the security inadequate, the Contractor shall furnish additional security satisfactory to the administering office, to the extent that the security is available.
- (I) *Representations*. The Contractor represents the following:
  - (1) The balance sheet, the profit and loss statement, and any other supporting financial statements furnished to the administering office fairly reflect the financial condition of the Contractor at the date shown or the period covered, and there has been no subsequent materially adverse change in the financial condition of the Contractor.
  - (2) No litigation or proceedings are presently pending or threatened against the Contractor, except as shown in the financial statements.
  - (3) The Contractor has disclosed all contingent liabilities, except for liability resulting from the renegotiation of defense production contracts, in the financial statements furnished to the administering office.
  - (4) None of the terms in this clause conflict with the authority under which the Contractor is doing business or with the provision of any existing indenture or agreement of the Contractor.
  - (5) The Contractor has the power to enter into this contract and accept advance payments, and has taken all necessary action to authorize the acceptance under the terms of this contract.
  - (6) The assets of the Contractor are not subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the Contractor. There is no current assignment of claims under any contract affected by these advance payment provisions.
  - (7) All information furnished by the Contractor to the administering office in connection with each request for advance payments is true and correct.
  - (8) These representations shall be continuing and shall be considered to have been repeated by the submission of each invoice for advance payments.
- (m) *Covenants.* To the extent the Government considers it necessary while any advance payments made under this contract remain outstanding, the Contractor, without the prior written consent of the administering office, shall not--

- (1) Mortgage, pledge, or otherwise encumber or allow to be encumbered, any of the assets of the Contractor now owned or subsequently acquired, or permit any preexisting mortgages, liens, or other encumbrances to remain on or attach to any assets of the Contractor which are allocated to performing this contract and with respect to which the Government has a lien under this contract;
- (2) Sell, assign, transfer, or otherwise dispose of accounts receivable, notes, or claims for money due or to become due;
- (3) Declare or pay any dividends, except dividends payable in stock of the corporation, or make any other distribution on account of any shares of its capital stock, or purchase, redeem, or otherwise acquire for value any of its stock, except as required by sinking fund or redemption arrangements reported to the administering office incident to the establishment of these advance payment provisions;
- (4) Sell, convey, or lease all or a substantial part of its assets;
- (5) Acquire for value the stock or other securities of any corporation, municipality, or Governmental authority, except direct obligations of the United States;
- (6) Make any advance or loan or incur any liability as guarantor, surety, or accommodation endorser for any party;
- (7) Permit a writ of attachment or any similar process to be issued against its property without getting a release or bonding the property within 30 days after the entry of the writ of attachment or other process;
- (8) Pay any remuneration in any form to its directors, officers, or key employees higher than rates provided in existing agreements of which notice has been given to the administering office, accrue excess remuneration without first obtaining an agreement subordinating it to all claims of the Government, or employ any person at a rate of compensation over \$\_\_\_\_\_ a year;
- (9) Change substantially the management, ownership, or control of the corporation;
- (10) Merge or consolidate with any other firm or corporation, change the type of business, or engage in any transaction outside the ordinary course of the Contractor's business as presently conducted;
- (11) Deposit any of its funds except in a bank or trust company insured by the Federal Deposit Insurance Corporation or a credit union insured by the National Credit Union Administration;
- (12) Create or incur indebtedness for advances, other than advances to be made under the terms of this contract, or for borrowings;
- (13) Make or covenant for capital expenditures exceeding \$\_\_\_\_\_ in total;
- (14) Permit its net current assets, computed in accordance with generally accepted accounting principles, to become less than \$\_\_\_\_\_; or
- (15) Make any payments on account of the obligations listed below, except in the manner and to the extent provided in this contract:

[List the pertinent obligations]

## 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:	Background	See Attachment Section at the end of this RFP
Attachment 4:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 5:	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 6:	APPENDIX A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents	See Attachment Section at the end of this RFP
Attachment 7:	APPENDIX B - Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP
Attachment 8:	<u>APPENDIX C - Current NARSA Case</u> <u>Report Form</u>	See Attachment Section at the end of this RFP
Attachment 9:	APPENDIX D - Current NARSA Repository Inventory	See Attachment Section at the end of this RFP
Attachment 10:	APPENDIX E - Current NARSA Registration Form	See Attachment Section at the end of this RFP
Attachment 11:	APPENDIX F - Description of the NARSA Database(s) and NARSA Inventory Management System	See Attachment Section at the end of this RFP
Attachment 12:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	See Attachment Section at the end of this RFP
	POSAL ATTACHMENTS: The following attac	chmonts must be completed where applicable, and

TECHNICAL PROPOSAL ATTACHMENTS: The following attachments must be completed, where applicable, and submitted with the Technical Proposal. They may be accessed at: <u>http://www.niaid.nih.gov/contract/forms.htm</u>

Title	Location
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

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

They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci. pdf
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Electronic Cost Proposal (Excel Workbook)	http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
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.) They may be accessed at: <u>http://www.niaid.nih.gov/contract/forms.htm</u>

<u>Title</u>	Location
Invoice/Financing Request InstructionsCost- Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Invoice/Financing Request and Contract Financial Reporting InstructionsCost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Financial Report of Individual Project/Contract, NIH 2706	http://www.niaid.nih.gov/contract/forms/nih-2706.pdf
Instructions for Completing Form NIH 2706	http://www.niaid.nih.gov/contract/forms/instructions270 6.pdf
Privacy Act System of Records System of Records No. 09-25-0200 is applicable to this RFP.	http://oma.od.nih.gov/ms/privacy/pa-files/read02system s.htm
Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checkl ist.pdf

#### PART IV - REPRESENTATIONS AND INSTRUCTIONS

#### SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K 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.

#### IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

#### 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 (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 legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.
- (f) Contract award. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
  - (2) The Government may reject any or all proposals if such action is in the Government's interest.
  - (3) The Government may waive informalities and minor irregularities in proposals received.
  - (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise

be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) 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)

#### b. NAICS CODE AND SIZE STANDARD

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

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

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

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

It is anticipated that One Award will be made from this solicitation and that the award will be made on or about <u>February 16, 2007</u>.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement, completion type contract for a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

#### d. 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 1.35 FTEs or 2,527 total labor hours per year (applied to a base year of 1872 hours) for the entire period of performance. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes. Offerors should state the standard number of hours that are equivalent to one full-time person year of effort as used in their business proposal.

#### e. 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.

#### f. 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.

#### g. 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.

#### h. 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.

#### i. PREPARATION COSTS

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

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

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

Program Director Office of Acquisitions, DEA NIH, NIAID, DHHS 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one (1) day of filing a protest with the GAO.

(End of Provision)

#### k. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

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

(End of provision)

#### 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 and Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents.

#### 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 and Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions**.

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

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, Proposal Summary And Data Record).

#### (4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, Technical Proposal Cost 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) Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

#### (6) **Evaluation of Proposals**

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

#### (7) 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.

#### (8) 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.

#### (9) Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (<u>http://www.hhs.gov/ocr</u>/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at:

#### http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

#### (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) Obtaining and Disseminating Biomedical Research Resources

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

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

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

http://ott.od.nih.gov/NewPages/64FR72090.pdf.

#### (a) Sharing Research Data

[Note: The NIH Guide announcement referenced below states that this policy is applicable to "all investigator-initiated applications with direct costs greater than \$500,000 in any single year." This is an overall grant policy which requires that an applicant must seek agreement by NIH to accept assignment of their application in advance of the submission date. As such, this policy has no correlation to the contract process, therefore, the threshold is not applicable to contracts. Thus, this article applies to <u>any</u> contract that may generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

#### (12) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

- a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and
- b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

#### (13) 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.

#### (14) ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

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

#### (15) Past Performance Information

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

A list of the last five (5) contracts completed during the past three (3) years and the last three (3) contracts awarded currently in process 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 that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

- 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 shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract over \$550,000.

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

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. 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.

#### (16) 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: <a href="http://www.arnet.gov/far/">http://www.arnet.gov/far/</a>.

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).
- d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

#### b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished (See Attachment 6, Appendix A). 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 <u>MUST</u> 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) 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, herein.

#### (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.

#### (5) Information Technology Systems Security

#### IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "Information Security."

The Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (<u>http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc</u>), the following requirements apply:

- (a) Information Type
  - [x] Administrative, Management and Support Information:
  - [] Mission Based Information:

(b) <u>Security Categories and Levels</u>

Overall	Level:	[x] Low	[] Moderate	[] High
Confidentiality	Level:	<b>[x]</b> Low	[] Moderate	[ ] High
Integrity	Level:	<b>[x]</b> Low	[] Moderate	[ ] High
Availability	Level:	<b>[x]</b> Low	[] Moderate	[ ] High

(c) <u>Position Sensitivity Designations</u>

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

- [] Level 6: Public Trust High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).
- [] Level 5: Public Trust Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
- [x] Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(d) Systems Security Plan

The offeror's proposal must:

a) Include a detailed plan of its present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. Offerors must use:
 NIH Systems Security Plan Template (detailed) at:

http://irm.cit.nih.gov/security/secplantemp.doc; or

NIH Systems Security Plan Outline (outline only) at:

http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc.

#### OR

(1) Include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

- (i) Security Awareness Training
- (ii) Logical Access Control
  - -Network (ex: firewall) -System (ex: network OS, tcp wrappers, SSH) -Application (ex: S-LDAP, SSL) -Remote Access (ex: VPN) -Monitoring and support (ex: IDS, pager, NOC)
- (iii) Protection against data loss
  - -OS security (ex: patch management, configuration)

-Application security (ex: patch management)

- -Database security
- -Back-up and recovery
- -Fault tolerance, high availability
- (iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
- (v) Physical Security
  - -Access control (ex: locks, guards)
  - -Power conditioning and/or UPS
  - -Air conditioning
  - -Fire protection

Include an acknowledgment of its understanding of the security requirements. Provide similar information for any proposed subcontractor developing or accessing an AIS.

The SSP that the offeror must submit with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

#### (e) Information Systems Security Training

DHHS policy requires contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the NIH Computer Security Awareness Training course (<u>http://irtsectraining.nih.gov/</u>), prior to performing any contract work, and on an annual basis thereafter, during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (<u>http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf</u>). This document provides information about information security training that may be useful to potential offerors.

(f) <u>Prospective Offeror Non-Disclosure Agreement</u>

The Government has determined that prospective offerors will require access to Federal information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

#### [] Level 6: Public Trust - High Risk [] Level 5: Public Trust - Moderate Risk

To be considered for access to Federal information, a prospective offeror must:

- a) Submit a written request to the Contracting Officer identified in the solicitation;
- b) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
- c) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the Federal information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

- (g) <u>References</u>
  - (1) DHHS Information Security Program Policy: <u>http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc</u>
  - (2) DHHS Personnel Security/Suitability Handbook: <u>http://www.hhs.gov/ohr/manual/pssh.pdf</u>
  - (3) NIH Systems Security Plan Template: <u>http://irm.cit.nih.gov/security/secplantemp.doc</u>
  - NIH Systems Security Plan Outline: <u>http://irm.cit.nih.gov/nihsecurity/Security\_Plan\_Outline.doc</u>
  - (5) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
  - (6) NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf

Appendix A-D: <u>http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf</u>

- (7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: <u>http://csrc.nist.gov/publications/nistpubs/index.html</u>
- (8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: <u>http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf</u>
- (9) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: <u>http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf</u>
- (10) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf

#### c. 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 rationale 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 \$550,000, 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) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]
  - (a) Exceptions from cost or pricing data.
    - (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.
      - (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
      - (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--
        - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
        - (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
        - (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
    - (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
  - (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
    - (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
    - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

#### (5) Salary Rate Limitation in Fiscal Year 2006

Offerors are advised that pursuant to P.L. 109-149, no NIH Fiscal Year 2006 (October 1, 2005 - September

30, 2006) 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. 109-149 applies only to Fiscal Year 2006 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I\* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 109-149 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 EXECUTIVE SCHEDULE SALARIES: <u>http://www.opm.gov/oca/06tables/indexSES.asp</u>

\*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 2006 Executive Level I Salary rates.

#### (6) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The offeror understands that:
  - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

- (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
- (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
- (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
- (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
- (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
  - (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
  - (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  - (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.
  - (4) A description of the method used to develop the subcontracting goals.
  - (5) A description of the method used to identify potential sources for solicitation purposes.
  - (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  - (7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
  - (8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

- (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
- (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
- (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

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

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

#### (7) 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 <a href="http://www.sba.gov/hubzone">http://www.sba.gov/hubzone</a>.

#### (8) Extent of Small Disadvantaged Business Participation

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

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

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

The Department of Commerce website for the annual determination for NAICS codes\* is: <u>http://www.arnet.gov/References/sdbadjustments.htm</u>.

\*Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.

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

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

#### EXAMPLE

#### Targets for SDB Participation - NAICS Subsector 223

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

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

#### (9) **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 <u>delivery</u> and <u>cost schedules</u> 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.

#### (10) 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:

#### HHSAR 352.232-75, Incremental Funding (January 2001)

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

#### (End of provision)

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

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

#### (11) 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

#### (12) **Proposer's Annual Financial Report**

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

#### (13) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

#### (14) 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**

#### GENERAL 1.

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost/price, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract. cost/price, past performance, and SDB Participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated Offeror. In any event, the Government reserves the right to make an award(s) 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.

#### 2. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable." and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

#### **TECHNICAL EVALUATION CRITERIA** 3.

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.

#### OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO APPENDIX A - Additional Technical Proposal Instructions OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION AND EVALUATION OF TECHNICAL PROPOSALS.

CRITERIA				
Α.	<u>TEC</u>	HNICAL APPROACH	55 points	
	1)	NARSA Case-History Registry and NARSA Repository	(15 points)	
		Soundness of the technical approach and adequacy appropriater	pess and feasibility	

Soundness of the technical approach, and adequacy, appropriateness, and teasibility of plans for the maintenance and expansion of the NARSA Case-History Registry and the NARSA Repository with respect to the following:

- Understanding of the types of S. aureus cases that have clinical, public health, a) and research relevance.
- The collection and reporting of S. aureus cases including collaboration with b) established surveillance networks.
- C) The identification, prioritization, and acquisition of isolates and reagents from domestic and international sources including the appropriate quality control/quality assurance procedures.

- d) Proposed protocols for receipt of isolates and reagents, determining their purity, confirming the identity of the isolates or reagents, growing additional quantities, and packaging and shipping isolates and reagents.
- e) The delivery of incoming isolates and reagents to ensure strain viability and stability.
- f) Compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous materials.
- g) The identification and correction of refrigerator/freezer malfunction.
- 2) NARSA Network, Scientific Working Group, and Communication Links (10 points)

Adequacy, feasibility, and soundness of the approaches for maintaining and updating the NARSA Network of investigators, establishing the Scientific Working Group, and establishing effective communication links with respect to the following:

- a) Updating the membership of NARSA investigators through outreach and communication.
- b) Utilizing the expertise of Scientific Working Group members to provide guidance on the conduct of NARSA functions.
- c) Proposed enhancements or modifications to the existing NARSA structure.
- d) Establishing effective communication links with NARSA members including the maintenance and updating of the NARSA website, and arrangements for annual NARSA Investigator meetings.
- 3) <u>Characterization of Isolates and New Methods for Determining the Minimal</u> <u>Inhibitory Concentrations (MIC) of Antimicrobials</u> (10 points)

Soundness, adequacy, appropriateness, and feasibility of the following:

- a) Understanding of the current technologies and methods for genotyping S. aureus isolates and for determining the MIC of the S. aureus isolates to vancomycin and other antimicrobials.
- b) The approach for identifying new methods for determining the MIC of antimicrobials as they become available.
- c) The plan for the design and conduct of comparative studies to evaluate antimicrobial susceptibility testing methods.
- 4) Data Management, Quality Control and Analysis (10 points)

Soundness, adequacy, feasibility, and appropriateness of the plans for the management, analysis, and quality control of NARSA data with respect to the following:

- Computerized relational database management system for inventory and tracking of NARSA Repository isolates and reagents and linkage to clinical data from NARSA Registry cases.
- b) Processing of requests and shipment of aliquots of the isolates and reagents.
- c) Data quality assurance/control program including the plan for training to ensure data quality.

#### 5) Information Dissemination

(10 points)

Soundness, adequacy, feasibility, and appropriateness of the plans for disseminating information on NARSA services and research resources to the scientific community.

#### B. <u>PERSONNEL</u>

Adequacy and suitability of the documented training, previous experience, expertise and availability of the Principal Investigator and proposed technical staff for conducting all aspects of the Statement of Work, including:

- 1) Previous experience in operating and coordinating a case registry and a biologics repository.
- 2) Knowledge and research experience in microbiology in order to provide technical experience.
- 3) Laboratory competence and working knowledge with safety regulations.
- 4) Working knowledge with database management, website maintenance and logistical meeting support.

#### C. PROJECT MANAGEMENT

Adequacy, thoroughness and appropriateness of the plans and procedures for overseeing, monitoring, and managing a state-of-the art NARSA repository and registry with respect to the following:

- 1) The proposed overall project organization and staffing and plans and procedures for close monitoring, coordination and management of all contract activities.
- 2) The proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments.
- 3) Communication with the NIAID Project Officer and Contracting Officer.

#### D. FACILITIES AND OTHER RESOURCES

- Availability, adequacy, and suitability of facilities, equipment and other resources necessary to safely operate and maintain the NARSA with respect to the following:
- 2) Receiving, characterizing, growing, storing, and shipping of hazardous and infectious agents while maintaining their activity and viability.

TOTAL POSSIBLE POINTS: 100 points

#### 15 points

15 poin ts

#### 4. 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 the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and 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.

#### 5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Complexity and variety of the work SDB concerns are to perform
- (c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

## SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

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

## 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-NIH-NIAID-DMID-07-11" "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	
Dominic Reeves	Dominic Reeves	
Contract Specialist	Contract Specialist	
Office of Acquisitions, DEA, NIAID, NIH	Office of Acquisitions, DEA, NIAID, NIH	
6700-B Rockledge Drive, Room 3214, MSC 7612	6700-B Rockledge Drive, Room 3214, MSC 7612	
Bethesda, Maryland 20817	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:

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

**TOTAL PAGE COUNT DOES** <u>NOT</u> **INCLUDE**: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

# 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.

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

Document Number of Copies		Page Limits
Technical Proposal and all Appendices (Appendices: All materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration and/or Intent.)	PAPEROne (1) unbound SIGNED ORIGINAL.Five (5) unbound COPIESELECTRONIC FILES ON CDTwenty (20) Compact Disks containing an electronic copy of the Technical Proposal in a Portable Document Format (PDF)[NOTE: 1 file on each disk.]	Limited to not-to- exceed <u>125</u> pages ( <b>including all</b> <b>appendices</b> )
Business Proposal	PAPEROne (1) unbound SIGNED ORIGINAL.Five (5) unbound COPIESELECTRONIC FILES ON CDThree (3) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF).[NOTE: 1 file on each disk.]	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal Excel Workbook	This Attachment should be submitted as a separate Excel file on the Business Proposal Compact Disk. See Section J, Attachment entitled <u>Breakdown of Proposed Estimated Costs (plus</u> <u>Fee) with Excel Spreadsheet</u> to access the Excel Workbook.	N/A

#### **PROPOSAL INTENT RESPONSE SHEET**

## **RFP No.:** NIH-NIAID-DMID-07-11 **RFP Title: Network on Antimicrobial Resistance in** *Staphylococcus aureus* (NARSA)

Please review the attached Request for Proposal. Furnish the information requested below and return this page by <u>March 10, 2006</u>. 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:

\_\_\_\_\_

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: Dominic Reeves RFP-NIH-NIAID-DMID-07-11 FAX# (301) 402-0972 Email: dreeves@niaid.nih.gov

## BACKGROUND

#### Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) RFP-NIH-NIAID-DMID-07-11

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), supports research related to the basic understanding of microbiology and immunology leading to the development of vaccines, therapeutics, and medical diagnostics for the prevention, treatment, and diagnosis of infectious diseases. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports a comprehensive extramural research program focused on the prevention and control of diseases caused by virtually all infectious agents (with the exception of the Human Immunodeficiency Virus). This includes basic research, such as studies of microbial biology and physiology; applied research, including the development of medical diagnostics; and clinical trials to evaluate experimental drugs and vaccines.

Infections due to *Staphylococcus aureus* are an important cause of morbidity and mortality in the United States. Vancomycin is often the last line of defense against methicillin resistant *S. aureus* (MRSA). Strains of *S. aureus* exhibiting intermediate susceptibility to vancomycin (VISA) first emerged in Japan in 1996 and in the United States in 1997. NIAID responded to this growing human health concern with the *Staphylococcus aureus* Plan (<u>http://www3.niaid.nih.gov/about/directors/congress/1999/0225.htm</u>), and, in 1999, with the establishment of the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) to promote communication and collaboration among researchers in the area of *S. aureus* antibiotic resistance. Strains of *S. aureus* fully resistant to vancomycin (VRSA) first appeared in 2002; however, only four cases have been reported to date. While the anticipated increased occurrence of vancomycin resistant strains that motivated formation of NARSA did not materialize, an unexpected emergence of community-acquired methicillin resistant *S. aureus* (CA-MRSA) has developed as a growing public health threat. These events demonstrate the difficulty in anticipating how or when an infectious disease will become a public health threat.

Since April 1999, the NARSA contractor has been Focus Diagnostics, Inc., Herndon, Virginia (previously Focus Technologies, Inc. and MRL Pharmaceutical Services) (NIAID Contract No. N01-AI-95359 issued April 12, 1999 and scheduled to expire on April 11, 2007). This contract established a repository of staphylococcal strains important to public health and research. This repository of staphylococcal isolates with associated historical case information is available to researchers to use to the fullest potential to increase knowledge and affect prudent clinical management approaches for minimizing antimicrobial resistance. NARSA also includes a website (www.narsa.net) and communication capacity to link basic scientists, epidemiologists, clinical microbiologists, and clinicians working in the area of staphylococcal diseases and antibiotic resistance, thereby encouraging collaborative research across disciplines of science, public health and medicine. Other NARSA activities include strain characterization; establishment and maintenance of a registry of *S. aureus* case information; evaluation of antimicrobial susceptibility testing methods; establishment of a NARSA Scientific Working Group to provide guidance and oversight of NARSA activities; and coordination of annual investigator meetings, which are open to NARSA investigators and invited participants.

The NARSA network of investigators currently consists of 190 NARSA Affiliate Members (researchers approved to order NARSA strains) and 71 NARSA Core Members (researchers receiving NIAID grant/contract support to study *S. aureus*). At present, the NARSA repository maintains 216 strains, and ships approximately 100 samples monthly, with one-third shipped abroad. Oracle databases store the information for the NARSA Repository, the NARSA Case-History Registry, and NARSA membership.

The purpose of this solicitation is to recompete the NARSA contract and make one (1) award for a term of seven (7) years. At the time of the current contract there was no systematic collection and distribution system for methicillin resistant *S. aureus* (MRSA) isolates. NARSA has filled this gap and it is important to maintain and update this resource for the research community. Researchers will continue to need ready and reliable access to well characterized isolates as well as an ability to easily communicate and interact with other researchers. The original NARSA repository collected isolates of interest for VRSA; however, in the contract to be awarded under this RFP, the repository will collect and distribute isolates of clinical, public health and research importance to antibiotic resistance in *S. aureus*. The repository will also acquire and distribute other reagents which the NARSA Scientific Working Group deem helpful to the research community in advancing research on antibiotic resistant *S. aureus*.

Additional information relevant to this solicitation is provided in the following Appendices:

- APPENDIX A ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND FORMAT FOR TECHNICAL PROPOSAL TABLE OF CONTENTS
- APPENDIX B ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS
- APPENDIX C CURRENT NARSA CASE REPORT FORM
- APPENDIX D CURRENT NARSA REPOSITORY INVENTORY
- APPENDIX E CURRENT NARSA REGISTRATION FORM
- APPENDIX F DESCRIPTION OF THE NARSA DATABASE(S) AND NARSA INFORMATION MANAGEMENT SYSTEM

## STATEMENT OF WORK

#### Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) RFP-NIH-NIAID-DMID-07-11

## INTRODUCTION

The purpose of this contract is to continue the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) to strengthen research on antibiotic resistance in *S. aureus* by facilitating communications within the research community and providing research resources to multidisciplinary investigators and clinicians studying and treating antibiotic resistant *S. aureus*. These resources are intended to address the public health problems the nation is facing with antibiotic resistance by fostering communication and facilitating research into mechanisms of antibiotic resistance. Under this contract, current NARSA activities will be continued with some activities redefined to ensure flexibility.

NIH is responsible for implementing a Department-wide information security program to assure that each information system and associated facility provides a level of security that is commensurate with the risk and magnitude of the harm that could result from the loss, misuse, disclosure, or modification of the information contained in the system. Each system's level of security shall protect the confidentiality, integrity, and availability of the information and comply with all security and privacy-related laws and regulations. The *HHS Information Security Program Policy and Handbook*, known as "Secure ONE HHS," provides a baseline of security policies for the Department. These policies apply to the Department, which includes Operating Division (OPDIV) and Staff Division (STAFFDIV) personnel, contractors, and other authorized users. All information technology related issues such as technical security, information security, personnel security, web management, application management, database management, electronic communications, electronic reporting, etc., defined within this contract is subject to the prescribed methods defined within "Secure ONE HHS."

## SCOPE

The scope of work to be performed by the NARSA includes:

- The maintenance, expansion, and updating of a multidisciplinary network of investigators focusing on *S. aureus* and other staphylococcal species that exhibit antimicrobial resistance.
- The establishment, maintenance and updating of a communication network to link basic scientists, epidemiologists, clinical microbiologists, and clinicians working in the area of staphylococcal diseases and antibiotic resistance, thereby encouraging collaborative research across disciplines of science, public health and medicine.
- The maintenance and expansion of a repository of staphylococcal isolates and reagents, and distribution of repository materials to the research and clinical communities to advance research on antibiotic resistant *S. aureus*.
- The maintenance and expansion of an international registry of cases of *S. aureus* infections of clinical, public health, and research relevance.
- The evaluation of new methods for antimicrobial susceptibility testing.

# This contract will NOT support a basic research program; such basic research is funded through other mechanisms, including investigator-initiated research grants.

The services to be provided under this contract shall be performed either directly by the Contractor or indirectly through subcontractors.

## **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.

Specifically, the Contractor shall carry out the following functions:

#### 1. Initial Transition

If applicable the successor contractor shall carry out the following tasks to provide for a safe, orderly and efficient initial transition:

- a. Provide for effective coordination at the start of the new contract period for the safe transfer of contractrelated materials, including:
  - 1) preserved isolate and reagent samples;
  - 2) the NARSA Repository database, software, domain name and documentation on the database/files;
  - 3) computerized files of accurate and updated information on NARSA members;
  - 4) computerized files of the NARSA Case-History Registry;
  - 5) NARSA website files;
  - 6) computerized files for isolate ordering system;
  - 7) computerized files for electronic bulletin board; and
  - 8) Government-furnished property.
- b. Complete the transition within the first 30 calendar days following the effective date of the contract. The functions of the NARSA must be maintained during the transition period, and receipt and distribution of isolates and reagents must not be interrupted at any time.

#### 2. NARSA Network of Investigators

Maintain, expand and update the existing NARSA network of investigators and clinicians studying and treating antimicrobial resistance in *S. aureus* as researchers enter or exit this area of study.

- a. Maintain the current multidisciplinary national and international network of basic scientists, clinical microbiologists, epidemiologists, and clinical investigators focusing on *S. aureus* and other staphylococcal species that exhibit antimicrobial resistance. Network members shall have access to isolates and reagents in the NARSA Repository, and to information contained in the NARSA Case-History Registry. This network includes the following:
  - 1) NARSA Core Members NIAID-supported investigators studying *S. aureus*; (currently, there are 71 Core Members);
  - 2) NARSA Affiliate Members non-NIAID supported investigators whose research is focused on issues relevant to antibiotic resistance in *S. aureus*; (currently, there are 190 Affiliate Members); and
  - 3) Registered Users –Core Members who have registered and all Affiliate Members.
- b. Revise, as necessary, the current NARSA Registration Form that allows investigators to apply for NARSA membership. Revisions must be approved by the NIAID Project Officer. In order to register in the NARSA Network, each applicant must supply the following information:

- 1) Name, title, institution, department, telephone, fax, and e-mail;
- 2) NIH intramural or extramural supported projects, if applicable;
- 3) Shipping information;
- 4) Certification of compliance with safety standards;
- 5) Certification that use of isolates is for intended research purposes only;
- 6) Agreement to comply with protection of human subjects, and humane care and use of animals;
- 7) Agreement for the assumption of shipping costs (not applicable for NARSA Core Members);
- 8) Agreement to acknowledge the NIH/NIAID and the NARSA in all publications and presentations;
- 9) Agreement to provide NARSA with a description of the planned use of the requested isolate with each isolate order form;
- 10) Agreement to notify NARSA of termination or departure from the institution at which the applicant is employed: and
- 11) A biographical sketch or curriculum vitae including a description of major research focus.
- c. Expand the network through communication and outreach to the *S. aureus* research community.
- d. Update contact information for NARSA network members and as researchers leave the field.

## 3. NARSA Scientific Working Group

Establish a NARSA Scientific Working Group to provide guidance and oversight of NARSA activities.

- a. Within thirty (30) calendar days of contract award, establish the NARSA Scientific Working Group (hereafter referred to as the Scientific Working Group) consisting of the Contractor's Principal Investigator, the NIAID Project Officer, a member of the Center for Disease Control and Prevention (CDC), and a representative selected by the Contractor from among the NARSA Core Members. Optionally, an additional NIAID staff member may serve on the Scientific Working Group to facilitate achieving programmatic objectives.
- b. Members of the Scientific Working Group shall have the depth and breadth of knowledge in antimicrobial resistance in *S. aureus* to:
  - 1) provide guidance on isolate and reagent acquisition;
  - 2) recommend approval of new NARSA Affiliate Members, with the final decision on membership to be made by the NIAID Project Officer;
  - 3) review and approve requests for isolates/reagents to be obtained from the NARSA Repository;
  - 4) evaluate new methods for determining the susceptibility of *S. aureus* isolates to antimicrobials;
  - 5) develop agendas for the annual NARSA investigator meetings; and,
  - 6) provide general oversight and advice to support the ongoing and planned activities of the NARSA.
- c. Plan and conduct monthly Scientific Working Group telephone conference calls.

#### 4. NARSA Communication

Establish, maintain, and update an effective communication network among investigators and clinicians working in the area of staphylococcal diseases and antibiotic resistance.

#### a. Communication with NARSA Members

1) Establish effective communication links with NARSA members through telephone (including capability for conference calls), facsimile receipt and transmission, and internet connectivity

including e-mail with full capability to transmit and receive text, data, and graphic files with appropriate security and encrypting, as necessary.

2) Prepare monthly (and more frequently, as necessary) e-mail messages and send to NARSA members and the NIAID Project Officer, providing an update on activities such as announcements of new members or new repository deposits.

## b. NARSA Website

1) Maintain and update the NARSA website (www.narsa.net) to provide information for NARSA members, the scientific community, the press, and the public on the emergence of antibiotic resistance in S. aureus and the activities of NARSA. The website shall also provide titles and links to articles appearing in the press and in scientific journals on the subject of antibiotic resistance in *S. aureus*. The website shall comply with Section 508 (see www.section508.gov) and comply with technical security, information security, personnel security, web applications issues, reporting, etc. as prescribed by the "Secure One HHS"

(http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc)

- 2) Provide hyperlinks to other relevant websites, particularly those of other networks addressing antimicrobial resistance, such as:
  - Centers for Disease Control Antibiotic resistance
  - Centers for Disease Control Vancomycin Intermediate Staphylococcus aureus
  - INSPEAR –International Network for the Study and Prevention of Emerging Antimicrobial Resistance
  - Surveillance for Emerging Antibiotic Resistance Connected to Healthcare (SEARCH) •
  - Canadian Committee on Antibiotic Resistance
  - U.S. Food and Drug Administration Site on Antibiotic Resistance •
  - European Antimicrobial Resistance Surveillance System (EARSS) •
  - Antimicrobial Resistance A World Organization Fact Sheet •
  - Alliance for the Prudent Use of Antibiotics (APUA)
  - **Report on Antibiotics** •
  - Center for Science in the Public Interest •
  - UK Public Health Laboratory Service (PHLS) •
  - Health Canada: Antibiotic Resistance •
  - Economics of Antibiotic Resistance •
- 3) Post information on the emergence of antimicrobial resistance on an electronic bulletin board on the NARSA website and update weekly, at a minimum.
- 4) Provide information and instructions on isolate donation by NARSA members and non-members.
- 5) Provide an electronic isolate and reagent ordering system that includes a description of the planned use of each requested isolate/reagent.
- 6) Provide an electronic bulletin board that shall allow isolate and reagent users and donors to interact directly through the NARSA website for request status information.
- 7) Recommend and obtain NIAID Project Officer approval for any substantial changes in content or format to the NARSA website.

### c. Annual NARSA Investigator Meetings

Organize and conduct annual two-day meetings of NARSA investigators, other researchers, clinicians and public health officials, as approved by the NIAID Project Officer. These meetings shall be held in the late winter or early spring within one hour commuting distance of Bethesda, Maryland. The Contractor shall develop the agenda based on recommendations provided by the NARSA Scientific Working Group.

- 1) Arrange for meeting and hotel space; prepare, assemble, and distribute materials prior to the annual meetings.
- 2) Requests to use contract funds to provide light refreshments and/or meals to either Federal or non-Federal employees must be submitted to the Project Officer, with a copy to the Contracting Officer, at least six (6) weeks in advance of the event. The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshment and/or meal costs; (d) the number of non-Federal and Federal attendees receiving light refreshments and/or meals; and (e) if the event will be held somewhere other than a Government facility, provide an explanation of why the event is not being held at a Government facility.

Refer to NIH Manual Chapter 1160\_1, Entertainment, for more information on NIH's policy on the use of appropriated funds for light refreshments and meals. (See SOP: <a href="http://www.niaid.nih.gov/ncn/sop/contracts/meals.htm">http://www.niaid.nih.gov/ncn/sop/contracts/meals.htm</a>)

- 3) Travel costs and per diem for all non-Federal attendees whose invitations are approved by the NIAID Project Officer shall be the responsibility of the Contractor.
- 4) Prepare, submit to the NIAID Project Officer, and distribute upon NIAID Project Officer approval, a summary of discussions at the annual meetings.

# 5. <u>NARSA Registry of Cases of Infections due to *S. aureus* with Clinical, Public Health and Research <u>Relevance</u></u>

- a. Maintain the existing NARSA Case-History Registry of cases of *S. aureus* infections related to antibiotic resistance (with 60 entries) and expand the Registry through the collection of new cases of *S. aureus* infections. This case information shall be collected from the clinician or researcher reporting the new case of infection.
- b. Within 45 days of contract award, review, and revise as necessary, the current Case Report Form (CRF) to capture clinical data about patients from whom strains of *S. aureus* with reduced susceptibility or resistance to antibiotics are isolated. Submit the CRF to the NIAID, and upon NIAID Project Officer approval, distribute the CRF to NARSA members.
- c. Provide NARSA members with an interface for electronic submission of the CRF data into the NARSA Case-History Registry database. CRF data from non-NARSA members shall be entered into the NARSA Case-History Registry database by the Contractor. Reporting of these cases to the NARSA Case-History Registry shall be voluntary. In an effort to collect standardized information about all reported cases, the Contractor shall contact the clinician or researcher reporting the new case. NARSA members shall participate in the collection of information on new cases identified in their home institutions.

- d. Establish effective and efficient means of communication with established surveillance networks, such as the National Nosocomial Infections Surveillance (NNIS) System -- <a href="http://www.cdc.gov/ncidod/dhqp/nnis\_pubs.html">http://www.cdc.gov/ncidod/dhqp/nnis\_pubs.html</a> and Project ICARE (Intensive Care Antimicrobial Resistance Epidemiology) -- <a href="http://www.sph.emory.edu/ICARE/index.php">http://www.sph.emory.edu/ICARE/index.php</a> -- as well as professional society and industry supported efforts in order to facilitate the collection of information and samples of isolates from relevant cases.
- e. Ensure that case information is anonymous and is not traceable back to the patients from whom the isolates were obtained.

## 6. NARSA Repository of S. aureus Isolates and Reagents

Maintain and expand the NARSA Repository, consisting of a collection of both new and historical isolates of *S. aureus* or other species important with regard to antibiotic resistance as determined by the Scientific Working Group. There are currently 216 strains in the NARSA Repository and it is expected that the Repository will expand by about 100 isolates per year.

#### a. Acquisition of Isolates and Reagents

- 1) Identify, under the guidance of the Scientific Working Group, *S. aureus* strains of clinical, public health, and research importance. Prioritize strain collection based on the needs of the research community.
- 2) Identify, under the guidance of the Scientific Working Group, reagents that are helpful to the research community in advancing research on antibiotic resistant *S. aureus*. Acquire reagents after receiving NIAID Project Officer approval. For purposes of this contract, reagents include but are not limited to the following biological materials:
  - a) Plasmids
  - b) Vectors
  - c) Oligonucleotides
  - d) Other genetic constructs
- 3) Review requests for isolate/reagent donations submitted through the NARSA website. Upon approval of the donation request, provide requestors with packaging and shipping instructions.
- 4) Provide donors with shipping containers for isolates and reagents that comply with current local, State, Federal and international transport regulations and pertinent International Air Transport Association/International Civil Aviation Organization Dangerous Goods Regulations. (See <u>http://www.iata.org/whatwedo/dangerous\_goods1</u>) The shipping containers must provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.

## b. Receipt and Processing of Isolates and Reagents

1) Obtain the appropriate licenses and permits required by local, State, and Federal authorities for the safe import, storage, and distribution of isolates and reagents. Additionally, the Contractor shall obtain the appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biohazardous isolates and reagents.

- 2) Provide for the delivery of incoming isolates and reagents to the NARSA Repository in a manner ensuring strain viability, including availability of personnel to pick up and store incoming shipments of isolates and reagents, as well as maintenance of stability and viability by providing the necessary temperature control in transit from the pick-up site to the NARSA Repository.
- 3) Develop and update standard correspondence for acceptance of isolates and reagents by the NARSA Repository.
- 4) Produce additional quantities of selected isolates and reagents as approved by the NIAID Project Officer. Dispense isolates and reagents into labeled vials with labeling specifications pre-approved by the NIAID Project Officer.
- 5) Confirm the identity and determine the purity of the isolates and reagents upon receipt.
- c. <u>Shipping and Distribution of Isolates and Reagents</u>
  - 1) Distribute isolates and reagents to NARSA members who have received Scientific Working Group approval for isolate/reagent use. Distribute isolates and reagents to non-NARSA members who have received approval for isolate/reagent use from both the Scientific Working Group and the NIAID Project Officer.
  - 2) Ensure shipping procedures are in compliance with all local, Federal, State, and international regulations.
  - 3) Reimburse shipping costs for isolate and reagent distribution to NARSA Core Members.
  - 4) Ensure that NARSA Affiliate Members and commercial firms assume the cost for the receipt of isolates and reagents.
  - 5) Provide for safe packaging, shipping and distribution of isolates and reagents to NARSA members within and outside of the U.S. so that such shipments are coordinated for receipt, using the most economical method of transport appropriate for maintaining stability/viability of the isolates or reagent.
  - 6) Provide data sheets packaged with outgoing isolates and reagents containing technical information, references and citations of the relevant information for safe handling and use of the isolates and reagents, and applicable safety standards.
  - 7) Coordinate all shipments so that viability, biological activity or purity of the isolates and reagents shall not be adversely affected. Send notification by electronic mail/facsimile/telegram to all foreign investigators to coordinate shipping and receiving of frozen and refrigerated isolates and reagents. Advise investigators in the most suitable manner of shipments and arrival dates. Establish a mechanism for notification by the requester of the date reagents were received and the condition of reagents upon receipt.
  - 8) Use shipping containers for isolates and reagents that comply with current local, State and Federal, and international transport regulations and pertinent International Air Transport Association/International Civil Aviation Organization Dangerous Goods Regulations. (See <a href="http://www.iata.org/whatwedo/dangerous\_goods1">http://www.iata.org/whatwedo/dangerous\_goods1</a>) Shipping containers must provide safety for maintaining environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.

- 9) Develop and update accompanying correspondence and documentation for distribution of isolates and reagents by the NARSA Repository.
- 10) Distribute materials (isolate and reagents) only to requesting organizations that agree to abide by NIAID-approved terms and conditions governing the receipt and use of the materials. These terms and conditions shall include:
  - a) Compliance with all relevant standards for safe handling and use of the materials.
  - b) Submission of a proposal, including biosketches of the recipient investigators, describing the planned use of the materials for review and approval by the NIAID Project Officer.
  - c) Certification by requesting organization of recipient investigator's intent not to use the materials in any unauthorized or unsafe way including compliance with all applicable laws, regulations, and Public Health Service research policies.
  - d) Receive materials from donors with donor's designation of a NIAID-approved use category (e.g. non-commercial use only, commercial use without separate donor agreement, commercial use with separate donor agreement).

#### d. Storage Facilities and Equipment

Provide facilities and equipment to receive and store isolates, including those that are potentially hazardous, in a way that will maintain their activity or viability. Provide sufficient capacity to ultimately store and maintain approximately 1000 isolates by the end of the contract period. This estimate includes the 216 current isolates, which will transfer with the award, as well as the projected accumulation and storage of an additional 600 isolates over the course of contract performance. Storage facilities for all isolates and reagents shall meet and remain current with local, State and Federal regulations.

- 1) Provide facilities with sterile conditions, as well as appropriate biosafety and biosecurity procedures for the handling of infectious agents.
- 2) Provide temperature-controlled floor space sufficient for the installation, storage and maintenance of equipment, and all items necessary for the NARSA Repository and distribution operation.
- 3) Store bulk and packaged isolates/reagents at 2 to 8 degrees C, at -10 to -20 degrees C, at -70 to -90 degrees C, liquid nitrogen conditions.
- 4) House the equipment in a temperature-controlled facility with the capacity to maintain a room temperature of 66 to 72 degrees F, when all equipment is operational.
- 5) Connect refrigerators/freezers to a central alarm system that is monitored 24-hours per day, seven days per week with measures in place to ensure that necessary personnel are notified in the event of a refrigerator/freezer malfunction. Emergency stand-by refrigerators and freezers shall be available in case of refrigerator and/or freezer mechanical failure. The facility shall have an auxiliary electric generator capable of operating all storage equipment for at least 48 hours for back-up in the event of electrical power failure. The central alarm system, air-conditioning and back-up generator shall be tested monthly and test results will be included in the Quarterly and Annual Progress Reports. The Contractor shall be responsible for repairing malfunctioning equipment or for arranging for its repair in order to return it to working order within 24 hours.

- 6) Assure safe handling of potentially toxic, radioactive, and biohazardous materials including the provision of protective garments, equipment, training, and monitoring to Contractor staff. Comply and remain current with all applicable health and safety regulations as outlined in <a href="http://www.cdc.gov/od/ohs/biosfty/biosfty.htm">http://www.cdc.gov/od/ohs/biosfty/biosfty.htm</a> in conducting the work set forth herein.
- 7) Maintain security 24-hour per day, seven days a week, that provides a secure environment for employees and materials within the facility so that only authorized personnel have access to the isolates.

## 7. Characterization of Isolates

- a. Genotype new isolates and uncharacterized NARSA Repository holdings using multilocus sequence typing, *spa* typing or related technique as determined by the NIAID Project Officer.
- b. Determine the minimal inhibitory concentrations (MIC) to vancomycin and determine MICs for other clinically useful or potentially useful antibacterial agents, including: other glycopeptides, penicillins, cephalosporins, and quinolones for new isolates and uncharacterized NARSA Repository holdings selected by the NIAID Project Officer. The MICs shall be determined using current Clinical and Laboratory Standards Institute (CLSI) criteria -- <u>http://www.clsi.org/</u>

## 8. <u>New Methods for Determining the Minimal Inhibitory Concentrations (MIC) of Antimicrobials</u>

- a. Identify new methods for determining the MIC of antimicrobials as they become available, and present them to the NIAID Project Officer for approval before evaluation.
- b. Provide an experimental plan for the comparison and evaluation of new method(s) to the Scientific Working Group for review, modification, and endorsement. Final approval of the plan shall rest with the NIAID Project Officer.
- c. Upon NIAID Project Officer approval of the experimental plan, conduct comparative studies of any newly available methods for determining the MIC of vancomycin or other relevant antimicrobials for *S. aureus* isolates.
- d. Distribute results of the completed study to the Scientific Working Group prior to acceptance by the NIAID Project Officer. This shall serve as the basis for selecting the methods to be used to characterize *S. aureus* isolates.

## 9. Data Management and Analysis and Computerized Inventory for the NARSA Repository

- a. Provide secure hardware and software systems to process, edit, store, retrieve, and analyze data generated by the NARSA Case-History Registry, NARSA Repository, NARSA website and NARSA membership database. The databases shall be structured to allow information to be retrieved in a manner for generation of reports and transfer of data to programs such as Microsoft Excel or Filemaker Pro.
- b. Maintain an on-going computerized inventory and distribution database and processing system to track and assist in the coordination of contract activities. The database shall be accessible to the NIAID Project Officer. This system should include modules to: track individual investigators' isolate and reagent acquisition and receipt; support production of standard reports, such as receiving and shipping; track publications by registrants acknowledging the NIAID NARSA Repository as a source of isolates and

reagents; and support specialized reports including the inventory of isolates and reagents, investigator affiliations and mailing lists.

- c. Maintain records for each isolate with reference to the data in the NARSA CRF for that isolate, including:
  - 1) the date and source/donor of the isolate;
  - 2) phenotypic parameters of the isolate including pattern of antimicrobial resistance;
  - 3) date of receipt;
  - 4) quality control information;
  - 5) storage conditions;
  - 6) storage location;
  - 7) restrictions, if any, on disposition and uses;
  - 8) how dispensed and to whom;
  - 9) when the isolate was shipped; and
  - 10) documentation of isolate receipt by the recipient.
- d. Maintain records for each reagent, including:
  - 1) the date and source/donor of the reagent;
  - 2) date of receipt;
  - 3) description of reagent;
  - 4) quality control information;
  - 5) storage conditions;
  - 6) storage location;
  - 7) restrictions, if any, on disposition and uses;
  - 8) how dispensed and to whom;
  - 9) when the reagent was shipped; and
  - 10) documentation of reagent receipt by the recipient.
- e. Develop and maintain a data quality control assurance program, including checks of the CRFs for completeness and overall quality, correction of forms, and database management, including data edits.
- f. Duplicate database files and programs for storage outside of the repository facility to ensure protection against the loss of data. The NARSA Repository database, NARSA Case History Registry, NARSA website files and NARSA membership files in their entirety, shall be completely documented and capable of being transferred to the Government without interruption.
- g. Provide for the security and safety of data on the registry isolates and reagents, and information related to the evaluation and use of the isolates and reagents. All information regarding the evaluation of the isolates shall be proprietary and treated as such. The NIAID Project Officer will be responsible for determining the level of information required for a particular isolate that will be made available for dissemination and to whom the information will be made available.

## 10. Manuscripts, Presentations, Press Releases and Information Dissemination

a. Prepare manuscripts, presentations and press releases involving data generated through the NARSA Case-History Registry and NARSA Repository. All publications shall acknowledge NIAID support. The NIAID Project Officer shall have access to all data generated under the contract and shall review and comment within 30 days of receipt of a draft on all resulting manuscripts, abstracts and press releases before publication or presentation. b. Promote awareness of the NARSA Case-History Registry and the availability of the services of the NARSA Repository throughout the scientific community using internet-based media, relevant scientific journals, presentations at scientific meetings, symposia and workshops.

## 11. Project Management

- a. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and management of all activities carried out under this contract, including effective communications with the NIAID Project Officer and Contracting Officer. This infrastructure shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring, and reporting project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors and/or consultants. This infrastructure shall also include a Project Manager to coordinate NARSA Repository activities, and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and any subcontractors.
- b. Assure effective communications with the NIAID Project Officer. This shall involve meetings with the Contractor's key personnel, including the Principal Investigator, and the NIAID Project Officer, at periodic intervals to be scheduled after contract award, to review the project status, progress and future plans. These meetings are to be arranged and coordinated by the Contractor.

## 12. Final Transition

- a. Six (6) months prior to the completion date of this contract, submit, for NIAID Project Officer and Contracting Officer approval, a Final Transition Plan that details the safe, orderly, efficient, safe and timely transfer of all contract-related materials to a subsequent contractor, if other than the incumbent contractor receives the contract award, or to the Government.
- b. Implement and coordinate the transition of contract resources, including the movement of stored isolate and reagent samples, data, and all Government-furnished property to a subsequent contractor, if other than the incumbent contractor receives the contract award, or to the Government.
- c. On or before the completion date of the contract, deliver to the Government or its designee the following items:
  - 1) preserved isolate and reagent samples;
  - 2) data files and program comprising the NARSA Case-History Registry;
  - 3) data files and programs comprising the NARSA Repository database and inventory management system;
  - 4) data files of the NARSA website;
  - 5) computer files containing accurate and up-to-date information on NARSA membership;
  - 6) labeled and inventoried paper files;
  - 7) all source code and object code developed, modified and/or enhanced under this contract;
  - 8) NARSA Registration Forms;
  - 9) NARSA Case Report Forms; and
  - 10) Experimental plan and results of completed studies for the completion and evaluation of new methods for determining the MIC of antimicrobials.

## [END OF STATEMENT OF WORK]

#### REPORTING REQUIREMENTS AND OTHER DELIVERABLES Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) RFP-NIH-NIAID-DMID-07-11

#### A. Technical Reports

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to Contracting Officer, unless otherwise specified.

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

#### 1. Quarterly Progress Report

Each quarterly report shall consist of:

- a) A cover page containing:
  - 1) Contract number and title;
  - 2) Period of performance being reported;
  - 3) Contractor's name and address;
  - 4) Author(s); and
  - 5) Date of submission
- b) An introduction covering the purpose and scope of the contract effort pertaining to the period of the report.
- c) A summary of the work performed during the reporting period including:
  - 1) An inventory report of the quantity of each isolate and reagent stored in the NARSA Repository as of the last day of each quarter.
  - 2) A summary of isolates and reagents shipped, with the following information for each isolate or reagent:
    - (a) Quantity of the isolate or reagent
    - (b) Date of shipment
    - (c) Date of receipt of shipment
    - (d) Name and address of the recipient
    - (e) Problems associated with any shipment and corrective actions taken
  - 3) A summary of isolates or reagents that were acquired during the quarter, with the following information for each isolate or reagent:
    - (a) Quantity of isolate and reagent
    - (b) Date of isolation
    - (c) Date of receipt
    - (d) Source of isolate or reagent
    - (e) Description of isolate or reagent

- (f) Quality control information and
- (g) Restrictions on disposition and use.
- 4) Cumulative list of publications by NARSA and registrants acknowledging the NIAID NARSA Repository as a source of isolates or reagents.
- 5) Maintenance problems encountered and corrective action taken.
- 6) Results of monthly tests on the central alarm system, air-conditioning system, and back-up generator.
- 7) Description of current technical or administrative problems encountered, their resolution or the proposed corrective action.
- 2. Annual NARSA Investigator Meeting Report

Following each annual NARSA investigator meeting, the Contractor shall submit a report summarizing discussions and recommendations from each annual meeting of the NARSA investigators.

3. Annual Progress Report

Each annual report shall consist of:

- a) A cover page containing:
  - 1) Contract number and title;
  - 2) Period of performance being reported;
  - 3) Contractor's name and address;
  - 4) Author(s); and
  - 5) Date of submission
- b) An introduction covering the purpose and scope of the contract effort pertaining to the period of the report.
- c) A summary of the work performed during the reporting period including:
  - 1) An inventory report of the quantity of each isolate and reagent stored in the NARSA Repository as of the last day of each contract year.
  - 2) A summary of isolates and reagents shipped, during the contract year with the following information for each isolate or reagent.
  - 3) Quantity of the isolate or reagent,
    - (a) Date of shipment
    - (b) Date of receipt of shipment
    - (c) Name and address of the recipient and
    - (d) Problems associated with any shipment and corrective action taken.

- 4) A summary of isolates or reagents that were acquired during the contract year, with the following information for each:
  - (a) Quantity of isolate or reagent
  - (b) Date of isolation
  - (c) Date of receipt
  - (d) Source of isolate or reagent
  - (e) Description of isolate or reagent
  - (f) Quality control information and
  - (g) Restrictions on disposition and use.
- 5) Cumulative list of publications by NARSA and registrants acknowledging the NIAID NARSA Case-History Registry and NARSA Repository as a source of data, isolates and reagents.
- 6) Maintenance problems encountered and corrective action taken.
- 7) Cumulative results of tests on the central alarm system, air-conditioning system, and back-up generator.
- 8) Description of current technical or administrative problems encountered, their resolution or the proposed corrective action.
- 9) Summary of the annual meeting of the NARSA investigators including who was present, what was discussed and what actions were recommended.

#### 4. Invention Reporting Requirement

All reports and documentation required by FAR Clause 52.227-11 including, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of 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 on the completion date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES, of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the completion date of the contract to the following address:

Contracting Officer Office of Acquisitions, DEA NIAID, NIH, DHHS 6700-B 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 Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

### 5. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the completion date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

#### 6. Final Report and Summary of Salient Results

The final report shall document and summarize the results of the contract for the entire period of performance. This report shall provide a final inventory of isolates and reagents and contain a cover page and the same information required above for quarterly reports. In addition, the final report shall include (not to exceed 250 words) a Summary of Salient Results achieved during the performance of the contract.

#### B. <u>Technical Reports Delivery Schedule</u>

If the Contractor is unable to deliver the reports specified hereunder by the required due date because of unforeseen difficulties notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate advance written notification of the anticipated delays with reasons therefore and a proposed revised due date. The revised due date must be acceptable to both the NIAID Project Officer and Contracting Officer.

Item	Type of Deliverable	Recipients &	Reports Due
1		Number of Copies	The Cost man of it last and to Com
1.	Quarterly Progress	2 Copies –	The first report is due on/before
	Report	Project Officer	The first report shall include any factional
		(PO)	part of the initial month. Thereafter, reports
		1 Original –	are due on/before the 15 <sup>th</sup> of the month
		Contracting Officer	following each quarterly reporting period. A
		(CO)	Quarterly Progress Report will not be due
		, ,	when the Annual or Final Report is due.
		1 Electronic Copy	*
		to both the PO and	
		CO	
2.	Annual Progress Report	2 Copies - PO	The first report is due on/before
		1 Original – CO	Thereafter, each Annual
			Report is due on/before the 30 <sup>th</sup> of the month
		1 Electronic Copy	following each anniversary date of the
		to both the PO and	contract. An Annual Progress Report will
		CO	not be due when the Final Report is due.

Copies of the technical reports shall be submitted as follows:

3.	Annual NARSA	2 Copies - PO	Due 30 calendar days after each Annual
	Investigator Meeting Report	1 Original – CO	NARSA Investigator Meeting.
	•	1 Electronic Copy	
		to both the PO and	
		СО	
4.	Final Transition Plan	2 Copies - PO	Due six (6) months prior to the contract
		1 Original – CO	completion date.
		1 Electronic Copy	
		to both the PO and	
		CO	
5.	Annual Utilization Report	1 Copy - CO	Due on/before the 30 <sup>th</sup> of the month following
			each anniversary date of the contract.
6.	Final Invention Statement	1 Copy – CO	On/before completion date of the contract.
7.	All reports and documentation including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification	1 Copy - OPERA	As required by FAR Clause 52.227-11.
8.	Final Progress Report and Summary of Salient Results	2 Copies - PO 1 Original – CO 1 Electronic Copy to both the PO and	Due on/before the completion date of the contract.
		СО	
9.	Source Code and object code	To Project Officer	Due on/before the completion date of the contract.

## C. Addressees

Project Officer:	National Institutes of Health NIAID, DMID, BMB 6610 Rockledge Drive Bethesda, MD 20892
Contracting Officer:	National Institutes of Health NIAID, DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612
OPERA:	Office of Extramural Inventions and Technology Resources Branch OPERA, NIH 6705 Rockledge Drive, Room 1040 A, MSC 7980 Bethesda, Maryland 20892-7980

#### D. Other Deliverables

These items are due to the Project Officer during the performance and at the end of the contract. They will be submitted to the PO for review at a time as appropriate to the task in the SOW:

- 1. NARSA Registration Forms;
- 2. NARSA Case Report Forms; and
- 3. the experimental plan and results of completed studies for the comparison and evaluation of new methods for determining the MIC of antimicrobials.

#### E. <u>Deliverables Due During Transition upon Contract Completion</u>

In accordance with the approved Final Transition Plan, the Contractor shall deliver to the Government or its designee on/before the completion date of the Contract, the following items:

- 1. preserved isolate and reagent samples;
- 2. data files and program comprising the NARSA Case-History Registry;
- 3. data files and programs comprising the NARSA Repository database and inventory management system;
- 4. data files of the NARSA website;
- 5. computer files of containing accurate and up to date NARSA membership list;
- 6. labeled and inventoried paper files;

## <u>APPENDIX A</u> - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

## Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) RFP-NIH-NIAID-DMID-07-11

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

The following additional Technical Proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions should be used as a guide for formatting and preparing the 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 material, appendices and attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of their proposals.

Offerors who propose 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 between the prime and subcontractor(s), and the expected advantages of such an approach.

**PROPOSAL PAGE LIMITATIONS:** Offerors are reminded that the total page limitation for the <u>entire</u> technical proposal package (including any appendices) is not to exceed 125 pages. [Two-sided pages count as 2 pages.] There are no page limitations for the business proposal.

## TECHNICAL PROPOSAL

## **SECTION 1**

- 1. 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.
- 2. PROJECT OBJECTIVES, NIH FORM 1688
- 3. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- 4. TABLE OF CONTENTS
- 5. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

## SECTION 2 - TECHNICAL PLAN/APPROACH

#### **Initial Transition**

1. The NARSA Repository, the NARSA Case History Registry and computer listing of NARSA Members are Oracle databases. A detailed description of all databases that will transition from the incumbent contractor is included in Attachment 11, Appendix F. The repository currently has 216 isolates and is expected to contain

300 isolates at the end of the current contract period, the contents of which are detailed in Attachment 9, Appendix D.

2. Provide a plan and timelines for transition of the current NARSA from the incumbent contractor in Herndon, Virginia, including movement of refrigerators/freezers containing isolates and reagents, all other Government-furnished property, and all data and data systems. Describe all coordination efforts required between the incumbent contractor and the offeror for the relocation tasks. Include plans for the continued conduct of ongoing operations and coordination with NARSA members for the initial transition period.

### NARSA Network of Investigators

- 1. Provide a plan for proposed outreach and communication activities and approaches to be utilized to expand the network of NARSA investigators studying and treating antimicrobial resistance in *S. aureus*. Provide a timeline for expansion and updating efforts throughout the proposed contract period.
- 2. Propose enhancements or modifications to the current NARSA network structure in order to accomplish the goals of this resource for the investigator, clinical care and public health communities.

#### NARSA Scientific Working Group

- 1. Describe the types of expertise required for members of the Scientific Working Group.
- 2. Discuss plans for utilizing the expertise of its members to provide guidance on the conduct of NARSA functions. <u>Do not identify in the Technical Proposal the names of any individuals proposed for the Scientific Working Group</u>.

#### NARSA Communication Network

- 1. Describe proposed approaches and methods to establish and maintain effective communication links with NARSA members.
- 2. Discuss plans to maintain and update the NARSA website on the World Wide Web and describe how the offeror will keep current with the advancing technology of the World Wide Web.
- 3. Discuss plans to arrange for Annual NARSA Investigator Meeting and hotel space; prepare, assemble, and distribute materials for the meetings; arrange travel for NARSA investigators to the meeting; and prepare and distribute minutes summarizing discussions at the meetings

#### <u>NARSA Registry of Cases of Infections due to S. aureus with Clinical, Public Health and</u> <u>Research Relevance</u>

- 1. Discuss plans for maintenance and expansion of the NARSA Registry of cases of infectious due to *S. aureus* with clinical, public health, and research relevance; outline procedures for the collection and reporting of cases; discuss the types of cases that have clinical, public health, and research relevance.
- 2. Outline approaches and methods to be used for maintaining and expanding collaborations with established surveillance networks for the collection of *S. aureus* case information.

## NARSA Repository of S. aureus Isolates and Reagents

#### 1. Acquisition of Isolates and Reagents

Discuss plans for identifying, prioritizing, and acquiring isolates and reagents from domestic and international sources. Discuss appropriate quality control/quality assurance procedures.

#### 2. Receipt, Processing, Storage, Shipping, and Distribution of NARSA Repository Isolates and Reagents

- a. Provide a summary of the offeror's knowledge, experience and competence in clinical microbiological methodology. Include a protocol delineating the processes proposed for receiving isolates and reagents; determining their purity; confirming the identity of the isolates or reagents; methods for aliquoting, labeling, and storing isolates and reagents, growing additional quantities; and shipping isolates and reagents.
- b. Discuss knowledge and experience in packaging/shipping biohazardous and etiologic agents nationally and internationally.
- c. Discuss knowledge and experience in procuring the appropriate import/export licenses and permits. Describe plans and procedures for packaging and shipping of isolates and reagents, and for receiving incoming isolates and reagents.
- d. Include a safety and health plan and a summary of safety and health operating procedures manual.
- e. Describe (a) the training plans and procedures for personnel handling infectious agents including *S*. *aureus*, HIV, and hepatitis B; (b) ongoing and planned programs for the training of personnel handling infectious biological material; (c) methods for dealing with accidents and monitoring for infection; and (d) safety standards applicable to particular reagents likely to be acquired.
- f. Provide a plan for the delivery of incoming isolates and reagents to the NARSA Repository in a manner ensuring strain viability, including availability of personnel to pick up and store incoming shipments of isolates and reagents, as well as maintenance of stability and viability by providing the necessary temperature control in transit from the pick-up site to the NARSA Repository.

## 3. Storage Facilities and Equipment

Describe and discuss facilities and equipment (available and to be acquired) for the conduct of this project including a floor plan. Include discussion to demonstrate your procedures and processes for achieving the requirements under this task.

Provide an action plan for identifying and correcting refrigerator/freezer malfunction, and a procedure for transferring isolates and reagents from malfunctioning refrigerators/freezers to functioning refrigerators/freezers.

## **Characterization of Isolates**

- 1. Describe current technologies and methods for genotyping *S. aureus* with the use of multilocus sequencing, *spa* typing or other related techniques.
- 2. Describe current technologies and methods for determining the minimal inhibitory concentrations (MIC) of antimicrobials and their strengths and weaknesses.

APPENDIX A

## New Methods for Determining the Minimal Inhibitory Concentrations of Antimicrobials

- 1. Describe the approach to identify new methods for determining the MIC of antimicrobials as they become available,
- 2. Provide a plan to evaluate and compare the brain heart infusion agar method with the Etest® method for determining the MIC of vancomycin in *S. aureus*. The plan should be in sufficient detail for a well qualified lab technician to carry out the analysis.

## Data Management and Analysis and Computerized Inventory for the NARSA Repository

## This contract will not support the purchase of general purpose automatic data processing equipment.

- Provide a plan to maintain and update the inventory and distribution database(s) using an appropriate menudriven commercially available relational database management system. This system should include modules to: track individual investigators' isolate and reagent acquisition and receipt; support production of standard reports, such as receiving and shipping; track publications by registrants acknowledging the NIAID NARSA Repository as a source of isolates and reagents; and support specialized reports including the inventory of isolates and reagents, investigator affiliations and mailing lists. The offeror must propose appropriate computer hardware and software for this requirement, and a plan for maintenance, data input and data backup. The offeror must provide data table shells or templates and propose outlines for reports that would be generated from information in the database. The data bases and online ordering is currently done with Oracle software.
- 2. Provide a plan and specific procedures for data quality control/assurance to ensure the accuracy and completeness of data and database management. Include plans for the provision of training to enhance data quality.

## Manuscripts, Presentations, Press Releases and Information Dissemination

- 1. Describe plans for the dissemination of public information concerning the availability of NARSA services and resources.
- 2. Describe the proposed editorial and technical support for the preparation and coordination of manuscripts, presentations, and press releases.

## Project Management

- 1. Provide a plan for project organization, staffing, and management in relation to the design, implemention, conduct, monitoring and completion of the tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel.
- Outline how the PI will communicate with the NIAID Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities). The cost estimate associated with meetings with the NIAID Project Officer shall be included in the Business Proposal.

#### **Final Transition**

Describe plans for the final transition of activities and contract-generated resources to the Government or a successor contractor. Includes timelines for the initiation and completion of all transition activities outlined in the Statement of Work and a description of the staffing requirements to execute an orderly, safe and timely transition.

#### **SECTION 3 - PERSONNEL**

- 1. Key Scientific and Technical Personnel: Describe the training, education, experience and qualifications of the PI and senior scientific and technical personnel proposed, as well as the percentage of the total time each will be committed to the project. This includes staff of the offeror and all proposed subcontractors and consultants. Please provide documentation to describe:
  - a. Key Scientific and Technical Personnel (limit CVs to 2-3 pages)
  - b. Qualifications and relevant training
  - c. Experience with projects of similar size and complexity
  - d. References to all relevant publications
  - e. Availability of all staff for the proposed project
  - f. Summary of ongoing and completed activities directly related to the requirements of the contract.
- 2. Other Personnel: Offerors should demonstrate the related experience and the role of other personnel as needed to address the requirements of the Statement of Work.

#### **SECTION 4 - FACILITIES AND RESOURCES**

The Technical Proposal should document the availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

- 1. Describe the location and features of the proposed facilities including a floor plan and a list of equipment and resources dedicated to the project (lease or ownership information should be provided)
- 2. Identify and describe ALL support resources, including IT systems that will be required to effectively complete the contract requirements.

## SECTION 5 – DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

## All offerors are advised to refer to Section L of the solicitation package for specific instruction regarding the following topics:

1. Privacy Act

Section L of the RFP specifies the minimum documentation requirements for Privacy Act compliance. All related documentation should be included in the proposal in a clearly marked section.

2. Data Sharing Plan

Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should include a plan for Data Sharing as required by the RFP.

APPENDIX A

## 3. Biohazard Safety

The Technical Proposal should include a plan for biohazard security requirements and training of personnel.

## 4. IT Systems Security

The website shall comply with Section 508 (see <u>www.section508.gov</u>) and comply with technical security, information security, personnel security, web applications issues, reporting, etc. as prescribed by the "Secure One HHS". (<u>http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc</u>)

## <u>APPENDIX B</u> - ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

## Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) RFP-NIH-NIAID-DMID-07-11

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, the technical evaluation criteria, and the RFP as a whole, in the development of their Business Proposals. The information requested in these instructions should 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**

## SECTION 1 – PROPOSAL COVERSHEET Form <u>NIH-2043 - PROPOSAL SUMMARY AND DATA RECORD</u>

## SECTION 2 – COST OR PRICE SUPPORT

Section J and Section L of the RFP specifies the attachments and minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

## SECTION 3 – UNIFORM COST ASSUMPTIONS

## 1) Travel

Assume one (1) trip to Bethesda, Maryland per year, for three (3) days, for 80 persons to participate in each annual NARSA Investigator Meetings.

Assume two (2) initial visits to Bethesda, Maryland, by two (2) contractor personnel to meet with the NIAID Project Officer will be necessary within six (6) months after the effective date of the contract. Subsequent meetings will be conducted via teleconference.

## 2) Special Shipping and Packaging

Assume that approximately 100 isolate or reagent samples will be shipped monthly from the NARSA Repository, involving an average of two-thirds domestic shipments and one-third international shipments. Anticipate approximately three (3) incoming shipments of isolates and reagents per month; as much as one-half could come from overseas each year. Assume that 40% of the requests for samples will come from commercial firms.

In accordance with the terms of the Statement of Work, allow for reimbursement of shipping costs for distribution to NARSA Core Members only; NARSA Affiliate Members and commercial firms are required to assume the cost for receipt of isolates and reagents. Any change to these terms and conditions for who will bear shipping costs will be determined by the NIAID Project Officer and may only be made through a bilateral modification to the contract.

### 3) Storage

The NARSA Repository will consist of approximately 300 isolates including the four (4) known fully vancomycin resistant isolates at the time of contract award. Additional isolates and reagents will be accrued at a rate of approximately eight (8) received monthly from domestic and international suppliers during each year of the contract to an estimated total of up to 1000 different isolates and reagents during the period of performance of the contract.

#### 4) Government Furnished Equipment (GFE)

Below is a list of equipment items that may be transferred to a successor contractor.

Item	Description	Manufacturer	Model/Type	Date Acquired (Mo/Yr)
1	Software for Database Server	Oracle Corporation	Oracle Server V8.0 for Microsoft Windows NT	May 1999
2	Software for Database Server	Advanced Business Solutions	MS Windows NT Server	June 1999
3	Software for NARSA File Server	Advanced Computer Concepts	V4.0 NT Server	June 1999
4	MS Exchange Server	Advanced Business Solutions	V5.5 5 User	June 1999
5	Software for NARSA Web Server	Oracle Application Server Domestic Edition	4.0 for Microsoft Windows NT	June 1999
6	Bar Code Label Printer	Intermec	Model 3240	March 2001
7	Computer Software	ChatSpace, Inc.	WebBoard 4.0, Oracle/Upgrade for WB4 Version 5.0	August 2001
8	Computer Software	Web Logic Server 7.0		August 2003
9	Refrigerator	Frigidaire	Model # FRT21P5AW1	June 2001
10	Laboratory Refrigerator with castors	Thermo Forma	Model #3777	October 2003
11	Lypholizer	ATR	FD3Freezer Dryer 554C	June 1999
12	Freezer	Forma Scientific	7400 Cryoplus 1 Storage System Model 7400	June 1999

#### 5) Other

Assume two (2) new methods to determine minimal inhibitory concentrations (MIC) will be evaluated and compared over the course of the contract.

Assume that the number of NARSA investigators will expand by thirty (30) members per year.

Assume that the NARSA Case-History Registry will expand at a rate of ten (10) cases per year.

## SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

#### 1) Small Business Subcontracting Plan

Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan is required to be submitted with the original business proposal. All related documentation should be included in the business proposal in a clearly marked section.

#### 2) Extent of Small Disadvantaged Business (SDB) Participation

Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be submitted with the original business proposal. All related documentation should be included in the business proposal in a clearly marked section.

#### 3) Past Performance Data, including references

Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be submitted with the original business proposal. All related documentation should be included in the business proposal in a clearly marked section.

## NARSA CASE REPORT FORM (Page 1 of 2)

Today's Date:		-
Focus Person Filling Out Form:		
Donor Site/Institution:		
Mailing Address:		
Name of Contact Person:		
Telephone Number:		
E-Mail Address:		
NARSA Temporary Strain Desig	gnation:	

\*\*\*TEAR OFF PORTION\*\*\*

This document contains confidential information. Use or disclosure of data contained on this page is strictly prohibited.

DO NOT PHOTOCOPY OR DUPLICATE THIS FORM

DATA ON THIS FORM IS NOT ALLOWED TO BE ENTERED INTO ANY DATABASE

## **<u>NARSA CASE REPORT FORM</u>** (Page 2 of 2)

Name of Donor Site/Institution:
This information is confidential and will be entered in a separate, secured, password protected database. Access will be restricted to the NARSA Scientific Working Group only. This information will NOT be accessible to Registered Users.
State of Donating Site: Country of Donating Site:
Patient Core Information:         Date of Isolation:         Age*:
*If the patient's specific age is 90 years old or above, please record the age as $\geq$ 90.
Gender: Male Female
Patient Location:      Inpatient ICUOutpatient
Patient Service at Time of Organism Isolation:
Medicine       Cardiothoracic Surgery       Other Surgery         Pediatrics       Hematology/Oncology       Other:
Culture Source (Check all that Apply):
Wound/ Skin/Soft Tissue       Bloodstream         Bone/Joint       Peritoneal Fluid         Device or Foreign Object       Respiratory         Other:
Reporting History (who, if anyone has been notified about the isolate):
City Health DepartmentCounty Health DepartmentState Health DepartmentCenter for Disease Control and PreventionNational Health Authority (if not U.S.)None Notified
TO BE FILLED OUT BY [NAME OF CONTRACTOR]
Has or Will Strain Be Submitted to the NARSA Repository?       Permanent Strain Designation #         Yes       No

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin MIC	Vancomycin	Accepted
					MIC	(Frozen)	MIC (Dried)	
		Mu 50; ATCC						
1	NRS 1	700699	S. aureus	Japan	8	8	8	9/12/2000
2	NRS 2	Mu 3; ATCC 700698	S. aureus	Japan	2	0.5	2	9/12/2000
3	NRS 3	HIP5827	S. aureus	Michigan	8	4	8	9/12/2000
4	NRS 4	HIP5836	S. aureus	New Jersey	8	4	4	9/12/2000
5	NRS 6	HIP04645	S. epidermidis	Wisconsin	8	4	4	9/12/2000
6	NRS 7	N/A	S. epidermidis	California	8	8	8	9/12/2000
7	NRS 8	HIP4680	S. epidermidis	Virginia	8	8	8	9/12/2000
8	NRS 9	HIP05979	S. haemolyticus	New York	8	4	8	9/12/2000
9	NRS 11	SA MER	S. aureus	France	4	2	2	10/6/2000
10	NRS 12	SA MER-S6	S. aureus	France	8	8	8	10/6/2000
11	NRS 13	SA MER-S12	S. aureus	France	8	4	4	11/3/2000
12	NRS 14	SA MER-S20	S. aureus	France	8	8	8	10/6/2000
		HIP06297;98-489						
13	NRS 17	smw	S. aureus	New York	8 (CDC)	8	8	11/3/2000
14	NRS 18	HIP06854	S. aureus	New Jersey	4 (CDC)	4	4	10/13/2000
15	NRS 19	HIP07256	S. aureus	Illinois	4 (CDC)	2	4	10/13/2000
16	NRS 21	HIP07920	S. aureus	Rhode Island	4 (CDC)	4	4	10/13/2000
17	<b>NRS 22</b>	USA600; HIP07930	S. aureus	New York	4 (CDC)	4	4	10/13/2000
18	NRS 23	HIP08926	S. aureus	California	4 (CDC)	4	4	11/3/2000
19	NRS 24	HIP09143	S. aureus	Ohio	4 (CDC)	4	4	10/13/2000
20	NRS 26	HIP09313	S. aureus	Texas	4 (CDC)	2	4	10/13/2000
21	NRS 27	HIP09433	S. aureus	Michigan	4 (CDC)	4	4	10/13/2000
22	NRS 28	HIP09662	S. aureus	West Virginia	4 (CDC)	2	4	10/13/2000
23	NRS 29	HIP09735	S. aureus	North Carolina	4 (CDC)	2	4	10/13/2000
24	NRS 34	N/A	S. epidermidis	California	16	4	4	11/3/2000

## NARSA Repository Inventory

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
25	NRS 35	LIM 1	S. aureus	France	2 (agar dil)	2	2	1/5/2001
26	NRS 36	LIM 2	S. aureus	France	8 (agar dil)	2	4	12/1/2000
27	NRS 37	LIM 3	S. aureus	France	8 (agar dil)	2	4	12/1/2000
28	NRS 39	99.3795.V	S. aureus	Scotland	8 (E test)	4	4	3/2/01
29	NRS 49	N/A	S. aureus	South Korea	8	4	4	1/5/2001
30	NRS 50	N/A	S. haemolyticus	Texas	6	4	4	1/5/2001
31	NRS 51	HIP09740	S. aureus	CA/NV	4 (CDC)	4	4	1/12/2001
32	NRS 52	HIP09737	S. aureus	CA/NV	4(CDC)	4	4	1/26/2001
33	NRS 53	N/A	S. epidermidis	Pennsylvania	8	4	4	1/26/2001
34	NRS 54	Br 15	S. aureus	Brazil	8	4	4	5/4/2001
35	NRS 56	Br 5	S. aureus	Brazil	8	8	8	5/4/2001
36	NRS 60	N/A	S epidermidis	Oregon	4	8	4	5/11/2001
37	NRS 62	N/A	S. haemolyticus	Texas	N/A	4	4	5/11/2001
38	NRS 63	LY-1999 0620-1	S. aureus	Oman	4 (Etest)	8	4	5/11/2001
39	NRS 64	LY-1999 0620-2	S. aureus	Oman	4 (Etest)	2	2	5/11/2001
40	NRS 65	LY-1999 0620-3	S. aureus	Oman	4 (Etest)	4	8	5/11/2001
41	NRS 68	N/A	S. aureus	Kentucky	4	4	2	5/25/2001
42	NRS 69	Shae 2	S. haemolyticus	Kentucky	4	4	4	5/25/2001
43	NRS 70	N315	S. aureus	Japan	N/A	0.5	0.5	6/29/2001
44	NRS 71	Sanger 252	S. aureus	UK	N/A	1	0.5	7/17/2001
45	NRS 72	Sanger 476	S. aureus	UK	N/A	1	1	7/17/2001
46	NRS 73	HIP 10540	S. aureus	Ohio	8 (CDC)	4	8	9/11/2001
47	NRS 74	HIP 10267	S. aureus	Maryland	4(CDC)	8	8	9/11/2001
48	NRS 76	C2000001227	S. aureus	Minnesota	8 (Etest)	4	4	9/18/2001
49	NRS 77	NCTC 8325;RN 1	S. aureus	USA	N/A	1	1	12/4/2001
50	NRS 79	L	S. aureus	Illinois	8	2	4	1/15/2002
51	NRS100	COL	S. aureus	USA	N/A	N/A	2	2/7/2002
52	NRS101	RP62A	S.epidermidis	USA	N/A	N/A	2	2/7/2002

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
50	NRS						0.5	0/40/0000
53	102	Reynolds	S. aureus	USA	N/A	N/A	0.5	2/19/2002
54	NRS 103	Becker	S. aureus	USA	N/A	N/A	1	2/19/2002
	NRS							
55	104	Cowan I	S. aureus	USA	N/A	N/A	0.5	2/19/2002
56	NRS 105	Wood 46	S. aureus	USA	N/A	N/A	1	2/19/2002
57	NRS 106	RN4220/pG01	S. aureus	USA	N/A	N/A	1	4/4/2002
58	NRS 107	RN4220/pG0400	S. aureus	USA	N/A	N/A	1	4/4/2002
	NRS		0. 44/040	00/1				1, 1,2002
59	108	A960649	S. aureus	France	N/A	N/A	1	4/4/2002
	NRS							
60	109	FRI361	S. aureus	N/A	N/A	N/A	0.5	4/30/2002
61	NRS 110	FRI472	S. aureus	USA	N/A	N/A	0.5	4/30/2002
	NRS					_		
62	111	FRI913	S. aureus	USA	N/A	N/A	1	4/30/2002
63	NRS 112	MN8	S. aureus	N/A	N/A	N/A	1	4/30/2002
	NRS							
64	113	MNDON	S. aureus	N/A	N/A	N/A	1	4/30/2002
65	NRS 114	МИНОСН	S. aureus	N/A	N/A	N/A	1	4/30/2002
	NRS		0. 000					1/00/2002
66	119	SA LinR #12	S. aureus	Massachusetts	N/A	N/A	2	7/9/2002
67	NRS 120	SA LinR #13	S. aureus	Massachusetts	N/A	N/A	2	7/9/2002

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
68	NRS 121	SA LinR #14	S. aureus	Massachusetts	N/A	N/A	2	7/9/2002
69	NRS 123	USA400; MW2;C1999000459	S. aureus	North Dakota	N/A	N/A	1	7/26/2002
	NRS							
70	115	N/A	S. haemolyticus	California	16 (Etest)	2	4	9/4/2002
	NRS		E					
71	116	N/A	S. haemolyticus	California	8 (Etest)	2	4	9/4/2002
	NRS							
72	118	N/A	S.aureus	California	4 (Etest)	8	8	9/4/2002
	NRS				6			
73	122	N/A	S. epidermidis	Maryland	(Etest,Vitek)	4	4	9/4/2002
	NRS			_	N./.			
74	127	N/A	S. aureus	Tennessee	N/A	N/A	2	10/10/2002
	NRS	4.000000	•	_	<b>N</b> 1/0			40/40/0000
75	156	A900322	S. aureus	France	N/A	N/A	1	10/10/2002
76	NRS 157	A980592	S. aureus	France	N/A	N/A	1	10/10/2002
70	NRS	A900392	S. dureus	Fidlice	IN/A	IN/ <i>F</i> A	1	10/10/2002
77	158	HT 2000 0319	S. aureus	France	N/A	N/A	1	10/10/2002
	NRS	111 2000 0010	0. 00.000	Trance	18/73	1 1/7 (	•	10/10/2002
78	161	HT 2000 0509	S. aureus	France	N/A	N/A	0.5	10/10/2002
	NRS							
79	162	HT 2000 0328	S. aureus	France	N/A	N/A	1	10/10/2002
	NRS							
80	128	NCTC8325 (RN0031)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS							
81	129	NCTC8325 (RN0153)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS							
82	130	NCTC8325 (RN2442)	S. aureus	N/A	N/A	N/A	1	11/12/2002

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS							
83	131	NCTC8325 (RN2887)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS							
84	133	NCTC8325 (RN0025)	S. aureus	USA	N/A	N/A	1	11/12/2002
	NRS							
85	134	NCTC8325 (RN0027)	S. aureus	USA	N/A	N/A	1	11/12/2002
	NRS		•		<b>N</b> 1/A	<b>N</b> 1/A		4.4.4.0.40.000
86	135	NCTC8325 (RN0450)	S. aureus	USA	N/A	N/A	1	11/12/2002
87	NRS 136	NCTC8325 (RN0451)	S. aureus	USA	N/A	N/A	1	11/12/2002
07	NRS	NCTC8323 (NN0431)	S. aureus	034			I	11/12/2002
88	137	NCTC8325 (RN0453)	S. aureus	USA	N/A	N/A	1	11/12/2002
	NRS		0. 44/040	00,1			•	11,12,2002
89	138	RN0833	S. warneri	N/A	N/A	N/A	2	11/12/2002
	NRS							
90	139	NCTC8325 (RN0981)	S. aureus	USA	N/A	N/A	1	11/12/2002
	NRS							
91	140	NCTC8325 (RN1389)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS							
92	141	NCTC8325 (RN3214)	S. aureus	N/A	N/A	N/A	1	12/24/2002
	NRS		-					
93	142	NCTC8325 (RN3763)	S. aureus	N/A	N/A	N/A	2	12/24/2002
	NRS		•	1104	<b>N</b> 1/A	<b>N</b> 1/A		44/40/0000
94	143	NCTC8325 (RN3984)	S. aureus	USA	N/A	N/A	1	11/12/2002
05	NRS		Sourous	NI/A	NI/A		1	11/12/2002
95	144 NRS	NCTC8325 (RN4220)	S. aureus	N/A	N/A	N/A		11/12/2002
96	145	RN4282	S. aureus	N/A	N/A	N/A	1	12/24/2002
	NRS		0. 44/040				•	12/21/2002
97	146	NCTC8325 (RN5843)	S. aureus	N/A	N/A	N/A	1	11/12/2002

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS	NCTC8325						
98	147	(RN6390B)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS	RN6432 ("Smith						
99	148	diffuse")	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS							
100	149	502A (RN6607)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS							
101	150	NCTC8325 (RN6709)	S. aureus	N/A	N/A	N/A	1	11/12/2002
100	NRS		0	1104	N1/A	N1/A		44/40/0000
102	151	NCTC8325 (RN6911)	S. aureus	USA	N/A	N/A	1	11/12/2002
100	NRS		0	N1/A	NI/A	N1/A		44/40/0000
103	152 NRS	WGB4316 (RN7044)	S. aureus	N/A	N/A	N/A	1	11/12/2002
104	153	RN8540	S. aureus	USA	N/A	N/A	1	11/12/2002
104	NRS	R100340	S. aureus	USA	IN/A	IN/A	I	11/12/2002
105	154	RN4850 (RN9121)	S. aureus	N/A	N/A	N/A	1	11/12/2002
100	NRS		0. 00.000	1 1 1 / / /	11/7	1 1/7 4	•	11/12/2002
106	155	502A (RN9120)	S. aureus	N/A	N/A	N/A	1	11/12/2002
	NRS		0.00.000					
107	164	A890259	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
108	165	A940441	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
109	166	A910669	S. aureus	France	N/A	N/A	2	12/27/2002
	NRS							
110	167	A970675	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
111	168	A850375	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS			_				
112	169	A920222	S. aureus	France	N/A	N/A	1	12/27/2002

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS					-		•
113	170	A960562	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
114	171	A970704	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
115	172	A970230	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
116	173	A970656	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS			_				
117	174	A900507	S. aureus	France	N/A	N/A	1	12/27/2002
440	NRS	1010505		_	N1/A	<b>N</b> 1/A	0	40/07/0000
118	175	A910565	S. aureus	France	N/A	N/A	2	12/27/2002
110	NRS	A050044		France	NI/A	NI/A		10/07/0000
119	176 NRS	A950211	S. aureus	France	N/A	N/A	1	12/27/2002
120	177	A960197	S. aureus	France	N/A	N/A	1	12/27/2002
120	NRS	A900197	S. aureus	Fidilue	IN/A	IN/A	I	12/21/2002
121	178	A910469	S. aureus	France	N/A	N/A	1	12/27/2002
121	NRS	71010400	0. 00/000	Trance	11/7 1	11/7	1	12/21/2002
122	179	A950319	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
123	180	A960254	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
124	181	A930472	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
125	182	A950085	S. aureus	France	N/A	N/A	1	12/30/2002
	NRS							
126	183	A980101	S. aureus	France	N/A	N/A	1	12/30/2002
	NRS							
127	184	A870192	S. aureus	France	N/A	N/A	1	12/27/2002

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS							
128	185	A890511	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS							
129	186	A900476	S. aureus	France	N/A	N/A	1	12/27/2002
	NRS		-					
130	187	A860325	S. aureus	France	N/A	N/A	1	12/30/2002
404	NRS	4.050000	•	_	N1/A			10/00/0000
131	188	A950206	S. aureus	France	N/A	N/A	1	12/30/2002
100	NRS 189	4040074		Бианаа	NI/A	NI/A	4	10/20/2002
132	NRS	A910371	S. aureus	France	N/A	N/A	1	12/30/2002
133	190	A970627	S. aureus	France	N/A	N/A	1	12/30/2002
155	NRS	A910021	S. aureus	Tance		IN/75	I	12/30/2002
134	191	A970698	S. aureus	France	N/A	N/A	1	12/30/2002
101	NRS	1010000	0. 44/040	Tranco			•	12/00/2002
135	192	C1998000370	S. aureus	Minnesota	N/A	N/A	2	1/29/2003
	NRS							
136	193	C1999000193	S. aureus	Minnesota	N/A	N/A	1	1/29/2003
	NRS							
137	194	C1999000529	S. aureus	North Dakota	N/A	N/A	1	1/29/2003
	NRS							
138	126	N/A	S. aureus	Massachusetts	4	4	4	3/27/2003
139	VRS 1	HIP11714	S. aureus	Michigan	> 128	> 256	> 32	1/29/2003
140	VRS2	HIP11983	S.aureus	Pennsylvania	32	64	> 32	3/27/2003
	NRS							
141	226	HT 20020028	S.aureus	France	N/A	N/A	1	4/7/2003
4.40	NRS		0	E				4/7/0000
142	227	HT 20020030	S.aureus	France	N/A	N/A	1	4/7/2003
140	NRS	UT 20020027	S aurous	Franco	NI/A	NI/A	1	4/0/2002
143	228	HT 20020037	S.aureus	France	N/A	N/A	1	4/9/2003

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
144	NRS 229	HT 20020044	S.aureus	France	N/A	N/A	1	4/7/2003
	NRS							
145	230	HT 20020057	S.aureus	France	N/A	N/A	1	4/7/2003
146	NRS 231	HT 20020058	S.aureus	France	N/A	N/A	1	4/7/2003
147	NRS 232	HT 20020065	S.aureus	France	N/A	N/A	1	4/9/2003
148	NRS 233	HT 20020067	S.aureus	France	N/A	N/A	1	4/7/2003
149	NRS 234	HT 20020073	S.aureus	France	N/A	N/A	1	4/7/2003
150	NRS 235	HT 20020075	S.aureus	France	N/A	N/A	1	4/7/2003
151	NRS 236	HT 20020141	S.aureus	France	N/A	N/A	2	4/9/2003
152	NRS 237	HT 20020167	S.aureus	France	N/A	N/A	1	4/7/2003
153	NRS 238	HT 20020180	S.aureus	France	N/A	N/A	1	4/7/2003
154	NRS 239	HT 20020204	S.aureus	France	N/A	N/A	2	4/7/2003
155	NRS 240	HT 20020229	S.aureus	France	N/A	N/A	1	4/7/2003
156	NRS 241	HT 20020233	S.aureus	France	N/A	N/A	2	4/7/2003
157	NRS 242	HT 20020238	S.aureus	France	N/A	N/A	2	4/7/2003
158	NRS 243	HT 20020252	S.aureus	France	N/A	N/A	1	4/7/2003

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS							
159	244	HT 20020261	S.aureus	France	N/A	N/A	1	4/7/2003
	NRS							
160	245	HT 20020320	S.aureus	France	N/A	N/A	2	4/7/2003
	NRS							
161	246	HT 20020330	S.aureus	France	N/A	N/A	1	4/7/2003
	NRS							
162	247	HT 20020331	S.aureus	France	N/A	N/A	1	4/7/2003
	NRS		_					
163	248	HT 20020338	S.aureus	USA	N/A	N/A	2	4/9/2003
101	NRS			_	<b>N</b> 1/A	<b>N</b> 1/A	•	
164	249	HT 20020341	S.aureus	France	N/A	N/A	2	4/7/2003
405	NRS		0	<b>F</b> rom e.e.	N1/A	N1/A	0	4/7/0000
165	250	HT 20020344	S.aureus	France	N/A	N/A	2	4/7/2003
166	NRS 251	HT 20020345	S ou rou o	France	N/A	N/A	1	4/7/2003
100	NRS	HT 20020345	S.aureus	Flance	IN/A	IN/A	I	4/1/2003
167	252	HT 20020351	S.aureus	France	N/A	N/A	1	4/7/2003
107	NRS	111 20020331	5. <i>aureus</i>	Tance			1	4/1/2003
168	253	HT 20020354	S.aureus	France	N/A	N/A	1	4/7/2003
100	NRS	111 20020001	0.00/000	Tranco	11/7	11/7	•	1/1/2000
169	254	HT 20020365	S.aureus	France	N/A	N/A	1	4/7/2003
	NRS							
170	255	HT 20020371	S.aureus	France	N/A	N/A	2	4/7/2003
	NRS							
171	256	HT 20020372	S.aureus	France	N/A	N/A	2	4/7/2003
	NRS							
172	257	HT 20020375	S.aureus	France	N/A	N/A	2	4/7/2003
	NRS							
173	258	HT 20020376	S.aureus	France	N/A	N/A	1	4/7/2003

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
174	NRS 259	HT 20020381	S.aureus	France	N/A	N/A	1	4/7/2003
1/4	NRS		S.aureus	Tance			I	4/1/2003
175	260	HT 20020390	S.aureus	France	N/A	N/A	1	4/7/2003
176	NRS	HT 20020206		France		N1/A	1	4/0/2002
176	261	HT 20020396	S.aureus	France	N/A	N/A	1	4/9/2003
177	NRS 262	HT 20020420	S.aureus	France	N/A	N/A	1	4/9/2003
178	NRS 263	HT 20020436	S.aureus	France	N/A	N/A	1	4/7/2003
170	NRS	111 20020430	S.aureus	Tance			I	4/1/2003
179	264	HT 20020438	S.aureus	France	N/A	N/A	2	4/7/2003
100	NRS			Cwitzerland	N1/A		0	4/7/2002
180	265	HT 20020444	S.aureus	Switzerland	N/A	N/A	2	4/7/2003
181	NRS 266	HT 20020455	S.aureus	France	N/A	N/A	2	4/7/2003
100	NRS			_	N1/A	N1/A		
182	267	HT 20020470	S.aureus	France	N/A	N/A	1	4/7/2003
183	NRS 269	GC 7647	S. aureus	USA	N/A	N/A	2	4/9/2003
	NRS							
184	271	N/A	S. aureus	UK	N/A	N/A	1	5/7/2003
	NRS							
185	196	No. 49	S. aureus	UK	N/A	N/A	1	7/3/2003
186	NRS 198	No. 56	S. aureus	UK	N/A	N/A	1	7/3/2003
100	NRS	No. 66; CN49I-	0. 00.000				1	.,0,2000
187	199	Staph:133	S. aureus	UK	N/A	N/A	1	7/3/2003
100	NRS	No. 150: 10007			N1/A		4	7/2/2002
188	201	No. 150; 12907	S. aureus	UK	N/A	N/A	1	7/3/2003

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS							•
189	202	No. 152; 16434	S. aureus	UK	N/A	N/A	1	7/3/2003
	NRS							
190	203	No. 153; 13111	S. aureus	UK	N/A	N/A	1	7/3/2003
	NRS							
191	204	No. 167; NCTC 6571	S. aureus	UK	N/A	N/A	1	7/14/2003
	NRS							
192	205	No. 208	S. aureus	UK	N/A	N/A	1	7/3/2003
	NRS							
193	207	No. 229	S. aureus	UK	N/A	N/A	1	7/3/2003
	NRS							
194	209	No. 315;28243	S. aureus	UK	N/A	N/A	1	7/14/2003
	NRS		_					
195	210	No. 326; KCM 187	S. aureus	UK	N/A	N/A	1	7/14/2003
	NRS							
196	211	No. 333	S. aureus	UK	N/A	N/A	2	7/14/2003
407	NRS	No. 044.0740	0		<b>N</b> 1/A	N/A		7/4 4/0000
197	212	No. 344; 2748	S. aureus	UK	N/A	N/A	1	7/14/2003
198	NRS 213			UK	N/A	N/A	1	7/4 4/2002
190	NRS	No. 348; 605E; G2	S. aureus	UN	IN/A	IN/A		7/14/2003
199	214	No. 359	S. aureus	UK	N/A	N/A	2	7/14/2003
200	NRS215	No. 425; 5441	S. aureus	UK	N/A	N/A	1	8/4/2003
200	NRS	110. 423, 3441	J. aureus				1	0/4/2003
201	216	No. 426; 5442	S. aureus	UK	N/A	N/A	2	7/14/2003
201	NRS	100. 420, 0442	0. 00/003		11/7	1 1/7 1	۷	7714/2000
202	217	No. 430; 5446	S. aureus	UK	N/A	N/A	1	7/14/2003
	NRS		0. 44.040				•	
203	218	No. 437; 96	S. aureus	UK	N/A	N/A	1	7/14/2003
	NRS							
204	219	No. 536	S. aureus	UK	N/A	N/A	2	7/14/2003

	NARSA	Alias	Organism ID	Location/origin	Reported	NARSA	NARSA	Date
Count	Strain #			(state/country)	Vancomycin	Vancomycin	Vancomycin	Accepted
	NRS							
205	220	No. 611; Wood-46	S. aureus	UK	N/A	N/A	1	7/14/2003
		No. 750; NCTC 6571;						
	NRS	ATCC 9144; NCIB						
206	222	6571; NRRL B-314	S. aureus	UK	N/A	N/A	1	7/14/2003
	NRS							
207	223	No. 784	S. aureus	UK	N/A	N/A	2	7/14/2003
	NRS							
208	224	no. 690; NAG9	S. aureus	UK	N/A	N/A	0.5	7/14/2003
	NRS	<b>aa</b> (	-					
209	225	no. 691	S. aureus	UK	N/A	N/A	1	7/14/2003
0.4.0	NRS		•		<b>N</b> 1/A	<b>N</b> 1/A		<b>T</b> /0 /0000
210	274	No. 55-1	S. aureus	UK	N/A	N/A	1	7/3/2003
211	NRS275	No. 55-2	S. aureus	UK	N/A	N/A	1	7/3/2003
212	NRS272	P1V44	S. aureus	Belgium	16	4	4	9/9/2003
213	NRS281	COLVA	S.aureus	Georgia	>128	N/A	>32	3/6/2004
214	NRS283	160013	S. aureus	UK	8	4	4	6/14/2004
215	VRS3	HIP13170	S. aureus	New York	64	>32	>128	6/20/2004
216	NRS382	USA100; 626	S. aureus	Ohio	N/A	N/A	2	04/06/05
217	NRS383	USA200; 96758	S. aureus	North Carolina	N/A	N/A	0.5	04/06/05
218	NRS384	USA300; 1114	S. aureus	Mississippi	N/A	N/A	1	04/06/05
219	NRS385	USA500; 95938	S. aureus	Connecticut	N/A	N/A	1	04/06/05
220	NRS386	USA700; 1078	S. aureus	Louisiana	N/A	N/A	1	04/06/05
221	NRS387	USA800; 1045	S. aureus	Washington	N/A	N/A	1	04/06/05
222	NRS402	HIP12864	S. aureus	Oklahoma	8	N/A	8	07/20/05
223	NRS403	HIP13057	S. aureus	Michigan	8	N/A	8	07/20/05
224	NRS404	HIP13036	S. aureus	Connecticut	8	N/A	8	07/20/05
225	VRS4	HIP13419	S. aureus	New York	>128	N/A	>128	07/20/05
226	NRS407	HIP12467	E. faecalis	Michigan	512	N/A	>128	In-Process
227	NRS408	HIP11713	S. aureus	Michigan	<1	N/A	1	In-Process

COLOR KEY		
		Genomic and Glycopetide-Intermediate
Strain occupying the Glycopeptide Resistant Repository	*NRS 1	Repositories
Strain occupying the		
Glycopeptide		
Intermediate		
Repository	NRS 77	Genomic and Research Repositories
* Strain occupying more than one		Glycopeptide Intermediate & Clinical
Repository	NRS22	Relevant Repositories
Strain occupying the Genomic Sequence Repository	NRS 101	Genomic and Virulent/Toxic Repositories
Strain occupying the Virulent/Toxin		Genomic and Clinical Relevant
Repository	NRS 123	Repositories
		Genomic and Antibiotic Resistant
Strain occupying the Antibiotic-Resistant Repository	NRS 70	Repositories
Strain occupying the Research		Genomic and Antibiotic Resistant
Repository	NRS 100	Repositories
Strain occupying the Clinical Relevant		
Repository	NRS 104	Virulent/Toxin and Historical Repositories
Strain occupying the Historical		
Repository		

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Do Not Write in This Space
Registration Form Number:
Approval Signature:
Date:
Name:
Department:
Telephone Number:
Fax Number:
Email Address:
Funding Support through NIH? Yes No
NIH Intramural Research Number:
NIH Extramural
Grant/Contract Number:
Shipping Information: Shipping information is not required for NARSA Core Investigators.
Shipping Address:
Note: Isolates will be shipped to the address specified below. Isolates cannot be
shipped to a post office box.
Shipping Company:
Shipping Company Account Number:

#### Certification of Compliance with Safety Standards Initials of Registrant:

I am aware that all isolates distributed by the NARSA Program are biohazardous and are specifically designated by a biohazard symbol (). I understand that the isolates might pose health risks to the environment, the community, and people handling or in the vicinity of the isolates. I certify that I am cognizant of and will employ the appropriate biosafety standards, including special practices, equipment, and facilities. I shall comply with all applicable institution and Government health and safety regulations and the guidelines detailed in *Biosafety in Microbiological and Biomedical Laboratories*, 4th Edition, GPO Stock No. 017-040-00547-4, May 1999, or the most recent revision of these guidelines. I will directly supervise all users of the isolates and I will assume responsibility for assuring that those users are cognizant of and comply with safety standards and good laboratory practices.

#### Certification of Use Initials of Registrant: \_

I certify that all isolates provided by the NARSA Program and any materials derived from said isolates will be used for research purposes only, in my laboratory only, at this institution only. If the purpose of my research area changes, I agree to notify [INSERT NAME OF CONTRACTOR] to receive approval for continued use of the isolates. Also, the isolates, or materials derived from them, will not be allowed to come into the possession of any people other than those engaged in research under my direct supervision who accept these restrictions.

Human Use Initials of Registrant: \_

I agree to comply with *Protection of Human Subjects*, Title 45, Code of Federal Regulations, Part 46. I agree that none of the isolates provided by the NARSA Program nor any derivatives of said isolates will be used in humans or for any clinical diagnosis.

#### Animal Use Initials of Registrant: \_

I agree that isolates provided by the NARSA Program and any materials derived from said isolates will be used in animals only as described in *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, October, 2000, or the latest version thereof. (Copies can be obtained from the NIH Division of Animal Welfare [301-594-2506] or the United States Government Printing Office, Publication No. 249-260). I understand that Institutional Animal Care and Use Committee (IACUC) approval is required prior to use of any NARSA isolates in research involving animal subjects.

Do you plan to use the isolates in animals? Yes \_\_\_\_ No \_\_\_\_. If yes, please provide the following:

Most Current Institutional Animal Welfare Assurance of Compliance Number:

Approval Date: \_\_\_\_\_

Assumption of Shipping Costs Initials of Registrant: \_\_\_\_\_

## Note: Shipping costs are not applicable for NARSA Core investigators

I agree to assume the costs of shipping isolates by providing my FedEx (or other carrier) shipping account number, or by making arrangements for prepaid shipments. I will confirm that the carrier is willing to ship biohazardous materials and can pick up shipments from the NARSA Program. No shipments will be made until my proposed shipping arrangements are accepted by the NARSA Program.

## Acknowledgement of Source Initials of Registrant: \_\_

I agree to acknowledge the National Institutes of Health/National Institute of Allergy and Infectious Diseases and its Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) Program in all publications and presentations of studies using isolates supplied by the NARSA Program. The preferred format for acknowledgments is as follows:

The following isolate was obtained through the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) Program: *<isolate name>* supported under NIAID/NIH Contract No. HHSN2662007

I also agree to provide copies of all publications and abstracts of presentations using data generated from the NARSA isolates or the NARSA Registry to [INSERT NAME] at the address provided with the registration instructions on the NARSA Website.

#### Reporting Agreement Initials of Registrant: \_\_\_

I agree to provide the NARSA Program with a description of the planned use of the requested isolates with each isolate order form, to be separately submitted for each isolate order I place. (This description of planned use is for internal tracking purposes only).

If my employment at the institution identified on the first page of this form is terminated, I further agree to provide written notification to the NARSA Program at least thirty (30) days prior to my departure from said institution. I understand that if I want to continue to order isolates from the NARSA Repository or to access scientific data on the NARSA Website after my departure, I will have to re-register with the NARSA Program under the auspices of my new institution.

## I Concur With All Statements Made Above

**Note:** The officer who cosigns below must be someone who can legally bind your institution, such as a president, vice-president, dean, or provost. A department chairman cannot serve as a cosigner for this form.

Registrant (Signature)	Officer of Institution (Signature)
Printed Name	Printed Name
Title	Title
Institution	Institution
Date	Date

# **BIOGRAPHICAL SKETCH**

Complete this form if you do not want to send a curriculum vitae or biographical sketch from a recent NIH grant proposal with the NARSA Registration Form.

Name:	
Title:	
Institution:	

## Education

List the degrees you have received in chronological order, ending with the most recent.

Institution	Location	Degree	Year Conferred	Field of Study

#### **Research and Professional Experience**

List your last three jobs in chronological order, ending with your current job.

Employer	Title	Dates of Employment	

#### Publications

List five articles you have published recently.

# **Research Focus**

Describe the focus of your research in 50 words or less.

# DESCRIPTIONS OF THE NARSA DATABASES AND INFORMATION MANAGEMENT SYSTEM

The NARSA Repository, NARSA Case-History Registry, and NARSA Member Database are currently being run on Oracle. A description of the NARSA Website and interface with the above mentioned databases is given below.

#### Description of the NARSA Web Site

## Introduction

This procedure outlines the basic configuration of the NARSA Web Site and the steps that the contractor followed while it created the initial NARSA Web Site. The current contractor has obtained and is utilizing the URL 'www.narsa.net' as the home page for the NARSA Web Site. The Home page is available on the World Wide Web and includes basic information about NARSA as approved for release by the Project Officer/Principal Investigator (PO/PI). Higher Level access is controlled through login accounts. An option for new users to register with NARSA and request a login account is available from the NARSA home page. In addition, an option for users (NARSA Core Investigators, Affiliates, and registered users) to login is available from the main home page. *Core Investigators* are defined as NIAID funded Staphylococci Investigators; *Affiliates* are defined as public health or medical researchers whose interests focus or are related to the NARSA initiative; and *Registered Users* are defined as anyone else who has been approved for access to NARSA Information. There are various levels of access based on the type of user associated with each account. Currently those levels include:

- 1. All information this is the highest level of access slotted for the PO/PI.
- 2. Core Investigator and Affiliate access this is the next highest access level that allows Core Investigators to view most of the information but not to change it.
- 3. Registered User access this is the next level of access that further limits access to information (there may or may not be any difference in the access to information between Core Investigators/affiliates and registered users but a separate user grouping is being established just in case). It basically allows viewing of non-controversial information and allows for submitting case report forms and perusing/requesting isolates from the NARSA repository.
- 4. General Public/Press access this is the lowest level of access and does not require the establishment of a user account. It allows access to the NARSA home page and all information that has been approved for release to the entire population worldwide.

User accounts, passwords, and access will be established for individuals approved by the PO/PI. A software user account management utility will be developed for use by the NARSA Administrator to establish new accounts, change privileges of existing accounts, manage passwords, and report on existing accounts and their actual access/usage.

In general all software tools/functionality will be presented and approved by the PO/PI prior to implementation. The lead Information Systems Specialist will attend planning and development meetings with the NARSA project team, analyze system requirements, and present a basic system concept. If the concept is agreed upon, the Lead Information Systems Specialist will direct the development of a Rapid Prototype of the concept utilizing the Web Application Developers and the Programmer Analysts. Once the basic user interface for the tool has been developed, the Lead Information Systems Specialist will present it to the PO/PI for design/interface approval. The Lead Information Systems Specialist will note any desired changes and then direct the development of the entire tool. The final version will be made available to the NARSA project team for testing and to the PO/PI for approval prior to implementation.

# Configuration

The purpose of this section is to inform offerors about the current configuration of the NARSA System and the software hardware that will be made available to a Contractor selected for award. The Government owns the software, hardware, databases and domain name currently in use and will these items available to the contractor selected for this award. In addition, the offerors may propose new configurations, upgrades and changes that may be necessary to provide quality information systems and service for the duration of the contract. Please keep in mind the short transition period from the current contractor (30 days) and that the functions of the NARSA must be maintained during the transition period. Receipt and distribution of isolates and reagents must not be interrupted at any time.

The current hardware and software configuration for the NARSA Web Site consists of:

- 1. A database server that stores NARSA Repository information on strains, storage, requests, case reports/status, and NARSA user access/management. The server provides data driven, dynamic web pages to the NARSA Web Site. The current system runs on MS Windows NT 4.0 with Oracle version 8.05, Oracle Web Application Server 4.0, and VirusScan 4.02.
- 2. A file/exchange server provides e-mail, outlook, backup and file storage capabilities. The current system runs on MS Windows NT 4.0 with MS Exchange Server 5.5, and VirusScan 4.02.

The table below is a list of system related Government Property that will be available to a contractor selected for
award. It a partial list of the Government Property. For a complete list see Appendix B of this solicitation:

Item	Description	Manufacturer	Model/Type	Date Acquired (Mo/Yr)
1	Software for Database Server	Oracle Corporation	Oracle Server V8.0 for Microsoft Windows NT	May 1999
2	Software for Database Server	Advanced Business Solutions	MS Windows NT Server	June 1999
3	Software for NARSA File Server	Advanced Computer Concepts	V4.0 NT Server	June 1999
4	MS Exchange Server	Advanced Business Solutions	V5.5 5 User	June 1999
5	Software for NARSA Web Server	Oracle Application Server Domestic Edition	4.0 for Microsoft Windows NT	June 1999
6	Bar Code Label Printer	Intermec	Model 3240	March 2001
7	Computer Software	ChatSpace, Inc.	WebBoard 4.0, Oracle/Upgrade for WB4 Version 5.0	August 2001
8	Computer Software	Web Logic Server 7.0		August 2003

Physical Access to the NARSA Web Site is currently provided through a T1 Internet connection and Firewall. This hardware Firewall is configured to limit the type of access allowed to the NARSA database and exchange servers to legitimate requests (HTTP, HTTPS, MAIL) and protect against IP spoofing, ping attacks, etc. In addition the system should have an automatic switch over to an ISDN 128KB backup in case the high speed connection goes down or has a significant amount of traffic.

## Security and Access Setup and Testing

The NARSA Web Site will be configured to allow a variety of access levels. The amount of information available and the ability to change information will be established for each security access level. A web site diagram showing all capabilities/information available and the navigation flow of the web site will be developed for each access level. These diagrams will be approved by the PO/PI prior to implementation. All changes to the web site diagram for a particular access level will be documented and approved prior to implementation. An on-line viewing mechanism will be developed for review of proposed web site changes (by access level) for review/approval of the PO/PI to facilitate more efficient change management and communication.

New users will be given a user name/password and assigned to the appropriate security access level based on PO/PI approval. The amount/level of security necessary for each access level will be discussed/approved by the PO/PI. Basic information about NARSA will be available via the home page to the world with no security restrictions (except for basic protection against hacking provided by the firewall). All detailed information concerning strains, etc will require the user to be approved, designated a user account and password, and assigned a security access level. An automated NARSA Web Site account request form would be available via the main home page along with a request status. When a new request is submitted, a request ID will be generated by the database and provided back to the requester. That request ID can be used to check the status of the account request.

Initially, all user account requests will be submitted to the PO/PI for approval/designation of security access level. As the NARSA Web Site's capabilities/popularity grows, a protocol will be established to allow the NARSA Administrator to automatically assign accounts with lower access levels to individuals as long as they meet specific criteria.

# Information Technology Systems Security Prospective Offeror Non-Disclosure Agreement

Request For Proposal (RFP) No:
(fill in RFP Number) Project Title:
(Fill in Title from RFP)
(Organization's name), intends to respond to the Government's Solicitation/Project title indicated above. The Government has determined that the
solicitation requires prospective offerors to have access to sensitive information in order to prepare an offer.
I,(Offeror Official name and title),
of (Organization's name),
on this day of, 20, on behalf of my organization hereby request access to the sensitive information described in Section L.III. of the RFP sited above.
I, the undersigned, understand that the Government has determined that any individual having access to the sensitive information described in the RFP must possess a valid and current Suitability Determination at the Level identified in Section L.III. of the RFP sited above.
<ul> <li>I, the undersigned, do hereby affirm the following:</li> <li>I have a valid and current Suitability Determination sufficient to access the sensitive information (copy of suitability determination attached.</li> </ul>
I will be the corporate official soley responsible for appropriately safeguarding the sensitive information while in the possession of (Organizations's name);
The sensitive information will be used solely for the purpose of preparing an offer;
I will not release, publish, or disclose the sensitive information to unauthorized personnel; and
• I will protect the sensitive information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information;
<ul> <li>18 U.S.C. 641 (Criminal Code: Public Money, Property of Records)</li> <li>18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)</li> <li>Public Law 96-511 (Paperwork Reduction Act)</li> </ul>
Signature of Prospective Offeror Official: Name of Prospective Offeror Official: Name of Prospective Offeror: Date:
Signature of Witness: Name of Witness: Date:

Copies Retained by: Contractor Official & Contracting Officer