AMENDMENT OF NIAID SOLICITATION "Management of Information Resources on Therapeutic Agents for HIV and Opportunistic Infections"

Solicitation Number: RFP-NIH-NIAID-DAIDS-07-27

Amendment Number: One (1)

Amendment Issue Date: Tuesday, October 24, 2006

Proposal Due Date: (Changed)

Tuesday, January 9, 2007 at 3:00 PM, Local

Time

Issued By: Jill M. Johnson

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This amendment provides questions and answers regarding the RFP, changes the NAICS code for this effort, corrects paragraph numbering in Section L, and corrects website links in cases where the links provided in the original RFP were obsolete or otherwise not functioning. The proposal due date and time are changed to January 9, 2007 at 3:00 p.m., local time. Offerors must acknowledge receipt of this amendment by identifying this amendment number and date of the amendment on each copy of the offer submitted. Failure to receive your acknowledgement may result in the rejection of your offer. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

Questions and Answers

- 1. Q: Is submission of the Proposal Intent Response sheet voluntary?
 - A: Yes, submission of the Proposal Intent Response sheet is voluntary.
- 2. Q: The NIH Form 1688-1 "Project Objectives" must be completed for every new R&D award. In some offices the Project Officer completes the 1688. Please explain why the Project Officer is not completing this form.
 - A: It is NIAID Policy that offerors complete form NIH-1688-1, "Project Objectives" and submit it with the proposal.

- 3. Q: Was the MDL database chosen at the behest of the government or was it the vendor's preference? Can the contractor migrate the database to another format over the course of the contract?
 - A: The MDL database was the choice of the Government. Offerors are not expected to suggest other systems since it is not a requirement of the RFP. See Section L.2.a.(5), Alternate Proposals, on page 34 of the RFP.
- 4. Q: There is at least an 8-month gap between the proposal due date and award of the contract. It is difficult to assure that key staff will be available at the time of contract award. Can the time between the proposal due date and award be shortened to ensure that proposed staff will still be available? If not, can NIAID recommend a method through which offerors can ensure that key staff will be available at the start of the contract?
 - A: While the procurement schedule cannot be reduced, the offeror may take into account that offerors that are within the competitive range that enter into negotiations with NIAID are asked to submit Final Proposal Revisions (FPR). In the event that any personnel changes have occurred since the time of initial proposal submission, there would be opportunity to raise this issue in negotiations prior to submission of the FPR.
- 5. Q: Does the past performance requirement on page 38 request at most five examples or at most five from the past three years AND an unspecified number of current projects?
 - A: Please see below revision to the Past Performance Information paragraph. Please provide 3 (three) examples from the past three years AND 2 (two) examples from current similar projects.
- 6. Q: Are the qualifications listed on page 49 to be included in the business proposal? If so, where?
 - A: Yes, the qualifications listed on page 49 should be included in the business proposal. Unless otherwise stated elsewhere in the RFP, you may include this information wherever it seems to most logically fit in the business proposal.
- 7. Q: Will the contractor be given access to electronic journals by the NIH or is the contractor expected to bear the costs of electronic journal access through some other means?
 - A: Yes, the Contractor will be given access to electronic journals by NIH.
- 8. Q: Is it considered valuable by the Government for the contractor to propose alternate/additional parameters for inclusion in the database that may be helpful to the research community (beyond those listed on attachment 4, page 3), or should the contractor expect to adhere to just those parameters already listed?
 - A: Yes, improvement is always encouraged within budgetary limits. But, this is not a requirement of the RFP. See Section L.2.a.(5), Alternate Proposals, on page 34 of the RFP.
- 9. Q: Does the proposal guidance in attachments 6 and 7 supplant or supplement the proposal guidance on pages 39 to 52?
 - A: The guidance in attachments 6 and 7 supplement the proposal guidance on pages 39 to 52.

Change of NAICS Code and Estimated Award Date

Item 5 of the RFP cover page, NAICS Code is hereby changed from 518210 to **541690**.

Item 12 of the RFP cover page, Period of Performance, is hereby replaced with the following:

Up to 7 years beginning on or about **September 25, 2007**.

Section L, paragraph 1.c, NAICS CODE AND SIZE STANDARD (1) and (2) are hereby replaced with the following:

- (1) The North American Industry Classification System (NAICS) code for this acquisition is **541690**.
- (2) The small business size standard is \$6.5 million.

Section L, paragraph 1.d, TYPE OF CONTRACT AND NUMBER OF AWARD(S), is hereby replaced with the following:

It is anticipated that one (1) award will be made from this solicitation and that the award will be made on/about **September 25, 2007**.

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

Past Performance Requirements

Page 38, Section L, paragraph 2.a.(13) (a), Past Performance Information, is hereby modified to read as follows:

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

A list of the last **three** (3) contracts completed during the past three (3) years and **two** (2) contracts currently in process that are similar in nature to the solicitation work scope. 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 the Requirement.
- 6. Contracting Officer's Name and Telephone Number

- 7. Program Manager's Name and Telephone Number
- 8. Standard Industrial Code or NAICS 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.

Corrections to Website Links

- 1. Page 12, Paragraph g.(2), the link referenced in the paragraph beginning with "For additional Information..." should read as follows: http://irm.cit.nih.gov/security/table3.htm.
- 2. Page 44, (d), the link referenced in the third paragraph beginning with "Additional security training..." should be replaced with the following: http://csrc.nist.gov/publications/. Using the search tool on the left-hand column, a search for "800-16", the document number, will yield the document entitled, "NIST Special Publication 800-16, Information Technology Security Training Requirements."
- 3. Page 44 (f), the second link referenced in the first paragraph beginning with "The offeror must include in the "Information Security" ..." should be replaced with http://csrc.nist.gov/publications/. Using the search tool on the left-hand column, a search for "800-53-rev1" will yield the document entitled, "Recommended Security Controls for Federal Information Systems."
- 4. Page 45, (i)(5) the link for NIST SP 300-18, Guide for Developing Security Plans for Information Technology Systems, should be replaced with http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf.
- 5. Page 45, (i)(7) the link for NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, should be replaced with http://csrc.nist.gov/publications/. Using the search tool on the left-hand column, a search for "800-53-rev1" will yield the subject document.
- 6. Page 4 of Attachment 5, Item 9. If you are having difficulty accessing the referenced link for NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form, you may try "cutting and pasting" the following link: http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf.

Correction of Paragraph Numbering

Page 28, Section L, 1.a.(3) through (6), is revised to read as follows:

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

- (b) 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.
- (c) (i) 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.
- (d) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (e) 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.
- (f) 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.
- (g) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (h) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (4) 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).
- (5) Restriction on disclosure and use of data.
 - (a) 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).

(b) 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.

(c) 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.

- (6) Contract award.
 - (a) 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 sub factors in the solicitation.
 - (b) The Government may reject any or all proposals if such action is in the Government's interest.
 - (c) The Government may waive informalities and minor irregularities in proposals received.
 - (d) 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.
 - (e) 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.
 - (f) 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.
 - (g) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
 - (h) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or sub line 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.
 - (i) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
 - (j) 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.
 - (k) 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)

Page 39, Section L, b, is revised to read as follows:

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) Technical Discussions

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

a) Project Objectives, NIH-1688-1

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

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

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

b) Statement of Work

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) Personnel

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR

HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

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

(4) Resumes

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

(2) Technical Evaluation

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

(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) 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

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 in its technical proposal 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

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

(6) Information Technology Systems Security

Information Security is applicable to this solicitation and the following information is provided to assist in proposal preparation.

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

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, Contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

Mission Based Information

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

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

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

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

[]	Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI)
Cont	ractor employees assigned to a Level 6 position are subject to a Background
Inves	stigation (BI).

[X] 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).

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. 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 Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

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

(d) <u>Information Security Training</u>

HHS policy requires Contractors/subcontractors 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/subcontractor employee has completed the NIH Computer Security Awareness Training course at: (http://irtsectraining.nih.gov/) prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course 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 (http://csrc.nist.gov/publications/. Using the search tool on the left-hand column, a search for "800-16", the document number, will yield the document entitled, "NIST Special Publication 800-16, Information Technology Security Training Requirements."). This document provides information about information security training that may be useful to potential offerors.

(e) Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

(f) NIST SP 800-26 Self-Assessment Questionnaire

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form at: (http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf - See Appendix B for submission format. NIST 800-26 assesses information security assurance of the offeror's internal systems security. This assessment is based on the Federal IT Security Assessment Framework and Draft NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, at:

http://csrc.nist.gov/publications/. Using the search tool on the left-hand column, a search for "800-53-rev1" will yield the document entitled, "Recommended Security Controls for Federal Information Systems."

<u>Subcontracts</u>: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

(g) <u>Draft Information System Security Plan</u>

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems

(http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

<u>Subcontracts</u>: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

<u>Note to Offeror</u>: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a Contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

(i) References

- (1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf
- (2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
- (3) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
- (4) NIST Special Publication 800-16, Information Technology Security Training Requirements:

 $\underline{http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf}$

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

- (5) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf
- (6) NIST SP 800-26, Revision 1, Computer Security: http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf
- (7) NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems: http://csrc.nist.gov/publications/. (Using the search tool on the left-hand column, a search for "800-53-rev1" will yield the subject document.)

- (8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories,
- Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf;
- Volume II, Appendices to Guide For Mapping Types of Information and Information Systems to Security Categories, Appendix C at:
- http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf and Appendix D at: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf.
- (9) 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.
- (10) FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems: http://csrc.nist.gov/publications/fips/fips199/FIPS-PUB-199-final.pdf.
- (11) FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems: http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf.

(7) Technical Questions

Offerors should submit all technical questions concerning this solicitation in writing to the contract specialist. NIIAID should receive all questions no later than 45 calendar days after the date of this solicitation. NIAID will answer questions which may affect offers in an amendment to the solicitation. NIAID will not reference the source of the questions.

END OF AMENDMENT #1 to RFP-NIH-NIAID-DAIDS-07-27