AMENDMENT OF NIAID SOLICITATION
"In vitro and Animal Models for Emerging Diseases and Biodefense"

Solicitation Number:	RFP NIH-NIAID-DMID-03-39
Amendment Number:	One (1)
Amendment Issue Date:	Wednesday, December 18, 2002
Proposal Intent Response Sheet Due Date:	Monday, December 30, 2002 **(CHANGED)**
Proposal Due Date: (CHANGED)	Thursday, February 4, 2003 at 4:00 PM Local Time
Issued By:	Paul D. McFarlane Senior Contracting Officer NIAID, NIH, DHHS Contract Management Branch, DEA 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Paul D. McFarlane, Contracting Officer E-Mail: pm24v@nih.gov

This amendment is issued to all potential Offerors.

The above numbered solicitation is amended as set forth below. The hour and date specified for receipt of proposals **HAS NOT** been extended. Offerors must acknowledge receipt of this and all other amendments, by identifying this amendment number (and any others) on each copy of any offer(s) submitted. Failure to receive your acknowledgement may result in the rejection of your offer. If, by virtue of this amendment, you wish to change an offer already submitted, such changes may be made by telegram, letter or e-mail, provided each telegram, letter or e-mail makes reference to this solicitation amendment number and is received prior to the opening hour and date specified. Except as provided herein, all terms and conditions of the solicitation remain unchanged and in full force and effect.

PURPOSE OF AMENDMENT: This amendment revises text in several parts of the solicitation, provides some information omitted from the original solicitation, provides two additional Statements of Work and provides a revised Proposal Intent Response Sheet.

1. The NAICS code for this acquisition is: 541710

2. In the RFP section titled, BACKGROUND/ STATEMENT OF WORK/NOTES TO OFFERORS, under CONTRACT TYPE, the two paragraphs are deleted and replaced with the following four paragraphs:

An Indefinite Delivery – Indefinite Quantity (IDIQ) type contract is planned. It is anticipated that multiple awards will be made for each part of this IDIQ Solicitation. The Contract will be in effect for seven (7) years. An IDIQ contract provides for an indefinite quantity, within stated limits, of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing orders with the contractor. Task orders will be issued to the pre-qualified pool of contractors for parts A, B, C, D, E or F based on the specific requirements of the task order. NIAID reserves the right to award to any contractor in the pool and to solicit to expand this pool as necessary throughout the seven (7) year ordering period.

NIAID intends to have all proposals submitted under this solicitation (whether submitted for one or more of the general task areas e.g. A through F) or under one or more of the 12 statements of work) subjected to a scientific/peer review where Offerors' technical capabilities will be evaluated. NIAID intends to establish six (6) separate competitive ranges, one for each of the task areas. The competing Offerors' individual business proposals will be subjected to a cost analysis during negotiations. Thereafter, task orders will be issued to those Contractors who are determined to offer the best overall value to the Government.

In accordance with FAR Part 16.504(a)(4), for this IDIQ contract, NIAID intends to issue orders under this contract (beyond the initial awards to result from this RFP) as needs arise. When requirements are established by the NIAID for any of the products or services within this contract, defined Task Orders will be issued, in writing, to one or more Contractor(s) qualified under the pertinent Part(s). The Contractor(s) will be required to prepare and submit a detailed proposal with milestones to perform the Task Order together with a detailed budget proposal within a specified number of calendar days. The resulting awards will include specifics on deliverables and reports. Because all Contractors for each Part (i.e. within each pool) will be pre-qualified by virtue of the initial scientific/peer review of their capabilities, there will be no further peer review required. In accordance with FAR 16.505(b)(1), it should be understood that individual task order proposals submitted by Contractors will be subjected to a technical evaluation, whereby NIAID Program and Contracts staff will ensure that the proposed efforts fit within the "original" capabilities of the Contractor as evaluated by the original Scientific/Peer review panel. Only the Contract Management Branch, NIAID will be authorized to issue orders under this requirement.

In response to this RFP, potential Offerors may submit proposals for one or more of the six (6) Parts described above. For Parts A and B, Offerors should propose as many organisms or groups of organisms as possible. Within Parts C, and D Offerors may submit proposals for one or more of the models using the same organisms/disease or models for more than one organism/disease. Offerors for Parts E and F should propose comprehensive services to cover all aspects of the Statement of Work. Each Offeror awarded a contract under a given Part will receive a guaranteed minimum dollar award at the time of contract award. The following scale sets forth the guaranteed minimum dollar awards per Part. Note that where the "actual" task order is priced at less than the stated minimum, that actual lower amount shall be awarded. In accordance with HHSAR 352.232-75 INCREMENTAL FUNDING (JAN 2001), NIAID reserves the right to incrementally fund task orders issued under this requirement.

Part A $ 75,000 Part B $ 75,000 Part C $100,000 Part D $150,000 Part E $100,000 Part F $100,000

3. Under the RFP section titled, BACKGROUND/STATEMENT OF WORK/NOTES TO OFFERORS, INTRODUCTION, the solicitation title "In Vitro and Animal Models for Emerging Infectious Diseases, including Bioterrorism Agents " should be replaced with, "In Vitro and Animal Models for Emerging Diseases and Biodefense."

4. Under the RFP section titled, BACKGROUND/STATEMENT OF WORK/NOTES TO OFFERORS, INTRODUCTION, the second paragraph is hereby deleted and replaced with the following:

The objective of this contract is to provide a range of developmental resources to bring new therapies and preventive measures from the laboratory to initial clinical testing in humans. The contract consists of six parts, listed below, which each contribute to the overall development effort. These contracts will provide a ready capacity in a number of needed areas and will be utilized as products become available for testing. Test articles that are found to have activity in Part A may progress through development using contractors from other parts. For Parts C, D, E and F, various vaccine concepts may be tested based on the following categories: (a) synthetic peptides, (b) recombinant subunits, (c) vector based vaccines, (d) virus-like particles/replicons, or (e) nucleic acid based vaccines. This acquisition will also provide some reimbursement for equipment and renovations of contractors' facilities directly related to the requirements of these contract efforts. This may include renovations up to BSL3+ and BSL4 for inhalational exposures. However, this reimbursement is NOT to be construed as "construction" reimbursement. There is no such reimbursement allowed for Parts D or E since these activities are not expected to deal with samples or animals that are infected with Category A, B, or C priority organisms.

5. Under the Notes To Offerors Organized by RFP Part, General Statement of Work for All Parts, NOTE #1 TO ALL OFFERORS is deleted and replaced with the following. [NOTE #1 TO ALL OFFERORS: All Offerors that receive an award are eligible for the guaranteed minimum. Offerors that receive awards for more than one Part will be eligible for the minimum awards for each Part. At the time of award, all Offerors that receive an award will receive the guaranteed minimum, plus any additional amounts over the minimum for the task orders awarded with the basic contract. Offerors that receive awards for models of more than one organism, or more than one model within a part (i.e. Parts A, C or D) will be eligible for a single minimum award for that Part. It is anticipated that the maximum total funding under this Contract will be between $25 - 40 million per year. After initial awards are made, whenever a need is established for any of the products or services under this Contract, a Task Order will be issued to one or more Contractor(s) qualified under that Part. Contractor(s) will submit a detailed proposal with milestones to perform the work stated in the Task Order together with a detailed budget proposal. The resulting awards will include specifics on deliverables and reports.]

6. Under Section L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS at TYPE OF CONTRACT AND NUMBER OF AWARD(S), the second paragraph is revised to read, "It is anticipated that awards from this solicitation will be multiple-year indefinite delivery, indefinite quantity contracts with cost-reimbursement completion-type task orders that are incrementally funded."

7. Under Section L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS at ESTIMATE OF EFFORT, the first sentence should be revised to read: "It is expected that completion-type task orders will be awarded under this contract."

8. Under Section L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS at COMPARATIVE IMPORTANCE OF PROPOSALS, the paragraph is deleted and replaced with the following: You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and all other factors being considered.

9. Under Section L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS at COMPARATIVE IMPORTANCE OF PROPOSALS, GENERAL INSTRUCTIONS, CONTRACT TYPE AND GENERAL CLAUSES, the paragraph is deleted and replaced with the following: It is contemplated that a indefinite delivery indefinite quantity contract with incrementally funded, cost-reimbursement completion-type task orders will be awarded. Any resultant contracts shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by the Public Laws, Executive Orders, or acquisition regulations in effect at the time of execution of the proposed contract(s).

10. Under Section L- INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS at COMPARATIVE IMPORTANCE OF PROPOSALS, GENERAL INSTRUCTIONS, SELECTION OF OFFERORS, the ninth paragraph is revised to read, "The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price Offeror or other than the highest technically rated Offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable), the extent of participation of Small Disadvantaged Businesses, and the cost analysis."

11. The following provision applies to this solicitation and is hereby incorporated into Section L under item 2.a. (General Instructions):

GUIDANCE REGARDING FEDERAL GOVERNMENT COLLABORATIONS

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

12. The following is hereby added to Section L under item 2.a., General Instructions:

PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

13. The following text is hereby added to SECTION L - General Instructions:

CARE OF LIVE VERTEBRATE ANIMALS

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

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

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory

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

b. The following information must be included in the Offerors technical proposal:

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

c. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

14. The following is hereby added to Section L under item 2.c. Business Proposal Instructions:

CERTIFICATION OF VISAS FOR NON-U.S. CITIZENS

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

15. The following text is provided to replace the GENERAL portion under SECTION M – Evaluation Factors for Award.

1. GENERAL
The major evaluation factors for this solicitation are technical, cost or price factors, Small Disadvantaged Business (SDB) Participation and Past Performance. Although technical factors are of paramount consideration in the award of the contract, cost or price, SDB participation and Past Performance are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make awards to those Offerors whose proposals provides the best overall value to the Government. NIAID intends to establish six (6) separate competitive ranges, one for each of the six task areas of this requirement. NIAID reserves the right to make only one award or none under each of the six task areas, based on the results of the technical and cost (and other factors) evaluation of each proposal.

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.

16. The following element is added under SECTION M – Evaluation Factors for Award as item #4. Current item #4 titled, "TECHNICAL EVALUATION CRITERIA" is hereby renumbered to be item #5.

4. PAST PERFORMANCE FACTOR
This is a non-scored element. An evaluation of each Offerors' available 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.

17. The following two Statements of Work (SOW) are hereby added to the solicitation. The first is the 3rd Part C SOW and the second is the 4th Part D SOW. There are a total of 12 SOWs in this solicitation and six (6) General Task Area Parts (i.e. A through F).

STATEMENT OF WORK
PART C (3)

SMALL ANIMAL MODELS FOR SELECTED PATHOGENS – VACCINIA, COWPOX, ECTOMELIA, OR RABBITPOX

The activity to be supported under this contract is the development and validation of small animal models, such as mice or rabbits, for vaccinia, cowpox, ectomelia, or rabbitpox infection and disease suitable for future testing of candidate vaccines and therapeutics.

[NOTE #1 to Offerors: Include all tests/studies that would be used to develop and validate the model. The proposal should be structured in terms of specific milestones to be accomplished. Provide a timeline. Offerors who have a model that is partially developed or who have developed models for similar viruses should include information about the model. Offerors should also include information about the approach to be used to develop a reproducible, standard model. If the Offeror will require assistance in obtaining strains of the virus, please indicate this in the proposal.]

1. Specifically, the contractor shall develop and standardize a small animal model of vaccinia, cowpox, ectomelia, or rabbitpox virus infection and disease suitable for screening and efficacy testing of new products including therapeutics, immunotherapies, diagnostics, and vaccines. Studies/measure may include, but are not limited to:
    a. Microbiological, histological, and immunologic analyses
    b. Disease progression and pathogenesis; clinical parameters
    c. Titration of viral stocks in animals; determination of infectious doses
    d. Optimization of model for relevant clinical endpoints

2. Optimize and standardize the model to meet the needs of testing efficacy of therapeutics and vaccines under the FDA's "animal rule": 21 CFR Parts 314 and 601 "New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible"

3. Provide all data, information, and records required to support regulatory filings to the Project officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

4. Complete all tasks as outlined in the General Statement of Work" for "In Vitro and Animal Models for Emerging Diseases and Biodefense."

STATEMENT OF WORK
PART D (4)

NON-HUMAN PRIMATE MODELS FOR SELECTED PATHOGENS – MONKEYPOX

The activity to be supported under this contract is the development and validation of a non-human primate model, such as cynomolgus macaque, for monkeypox virus infection and disease suitable for future testing of candidate vaccines and therapeutics.

[NOTE #1 to Offerors: Include all tests/studies that would be used to develop and validate the model. The proposal should be structured in terms of specific milestones to be accomplished. Provide a timeline. Offerors who have a model that is partially developed or who have developed models for similar viruses should include information about the model. Offerors should also include information about the approach to be used to develop a reproducible, standard model. If the Offeror will require assistance in obtaining strains of the virus, please indicate this in the proposal.]

1. Specifically, the contractor shall develop and standardize a non-human primate model, such as cynomolgus macaques, of monkeypox virus infection and disease suitable for screening and efficacy testing of new products including therapeutics, immunotherapies, diagnostics, and vaccines. Studies/measure may include, but are not limited to:
    a. Microbiological, histological, and immunologic analyses
    b. Disease progression and pathogenesis; clinical parameters
    c. Titration of viral stocks in animals; determination of infectious doses
    d. Optimization of model for relevant clinical endpoints

2. Optimize and standardize the model to meet the needs of testing efficacy of therapeutics and vaccines under the FDA's "animal rule": 21 CFR Parts 314 and 601 "New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible"

3. Provide all data, information, and records required to support regulatory filings to the Project officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

4. Compete all tasks as outlined in the "General Statement of Work" for "In Vitro and Animal Models for Emerging Diseases and Biodefense."

Replace the "Proposal Intent Response Sheet" SECTION J – List of Attachments, with the attached version dated October 22, 2002. Even if you have completed and provided this form earlier, we appreciate your resubmitting it.

NIAID PROPOSAL INTENT RESPONSE SHEET

RFP: NIH-NIAID-DMID-03-39 TITLE: In vitro and Animal Models for Emerging Diseases and Biodefense

Please complete and return this page by **Monday, December 30, 2002**. NIAID appreciates knowing if your organization intends to submit a proposal, as this will assist the NIAID in planning for proposal evaluation.

[ ] OUR ORGANIZATION **INTENDS** TO SUBMIT A PROPOSAL Your expression of intent is not binding.
[ ] OUR ORGANIZATION **DOES NOT INTEND** TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASON(S):

_____

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

Name of Proposed Project Director or Principal Investigator (print):
_____
Telephone and FAX Number and E-mail Address: _____
Signature/Date: _____

Since your proposal will be submitted electronically, include the name and e-mail of the individual to whom NIAID should provide electronic proposal instructions (i.e. login code and password).

Name, Title: _____
Telephone and FAX Number and E-mail Address: _____

List individuals (currently on staff with your institution) whom you plan to name in the proposal. Identify your collaborators, subcontractors and/or consultants. List the names of individuals (currently on staff) whom they plan to include in their proposal(s). Use extra pages if necessary. The NIAID uses this information for proposal review planning, specifically, to create a list of potential review panelists. The NIAID is careful to avoid conflicts of interest when assembling these panels. Therefore, it's important that you only name those institutions and individuals most likely to be part of your proposal. Contact the individual named below with any questions.

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Identify the specific work statement(s) and/or the *general* task area part(s) for which you intend to submit a proposal(s). Note that there are twelve (12) Work Statements and six (6) General Task Area Parts A through F.

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COMPLETE AND RETURN THIS SHEET VIA FAX OR E-MAIL TO:
NIAID, NIH, DHHS
Contract Management Branch, DEA
Attention: Paul D. McFarlane, Contracting Officer
Reference: RFP NIH-NIAID-DMID-03-39
6700-B Rockledge Drive, MSC 7612, Room 2230
Bethesda, MD 20892-7612, FAX (301) 402-0972, Email: pm24v@nih.gov

FORM VERSION DATE: October 22, 2002

END OF MODIFICATION #1 TO RFP NIH-NIAID-DMID-03-39