Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

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

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 541710 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** [42,536]
NIH-NIAID-DMID-04-22	[ ] Yes [X] No		

TITLE: Assessing Safety of Cell Substrates and Vaccine Components

Issue Date: **November 24, 2003**	***Due Date:*** ***March 1,*** **2004** ***Time:*** **4:00 PM, EST**	***Technical Proposal Page Limits:*** [X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:	[X] ***We reserve the right to make awards without discussion.***	
Paul D. McFarlane Acting Chief Preclinical Research Contract Branch CMP, DEA, NIH, NIAID, DHHS 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	***NO. OF AWARDS:*** [ ] Only 1 Award [X] Multiple Awards	***PERIOD OF PERFORMANCE:*** 5 years beginning on or about 09/30/2004

Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT **-- Robert Singman** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: Direct **301-451-2607** ***Main*** **301-496-0612**	***Fax*** **301-402-0972**	***E-Mail*** **RSingman@niaid.nih.gov**

Updated thru FAC 97-25 (05/02/01)

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INTRODUCTION/BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

Assessing Safety of Cell Substrates and Vaccine Components

Introduction

This RFP, "Assessing Safety of Cell Substrates and Vaccine Components," solicits proposals for the development, characterization and validation of *in vitro* assays and *in vivo* animal models to assess the safety of cell substrates and vaccine components that are being considered for use in vaccine manufacturing. The need for contemporary *in vitro* assays and *in vivo* animal models has arisen from 1) the development of vaccine candidates that can only be grown in cell substrates and/or require use of excipients or adjuvants that have not previously been used to manufacture licensed vaccines, and 2) previously unrecognized theoretical safety questions. For example, few tests are available to specifically assess certain safety issues that are unique to new cell substrates. These issues include tumorgenicity of the whole cell substrate, oncogenicity of the cellular DNA, and the detection of latent/occult adventitious agents in the cell substrate. Experimental data are needed regarding these issues in order for manufacturers and regulatory agencies to meaningfully assess and analyze the safety of vaccines manufactured in these new cell substrates. The focus of this RFP is to develop both *in vitro* assays and *in* vivo animal models to assess current and future safety concerns that arise regarding vaccines and vaccine manufacturing and/or formulation, including 1) assessing the tumorgenic potential of cell substrates; 2) assessing the oncogenic potential of cell substrate DNA; and 3) screening for latent/occult adventitious agents in cell substrates.

This RFP comprises five separate parts, each focusing on a specific area of *in vitro* assay development or *in vivo* animal model development:

Part A: Develop, characterize and validate *in vivo* animal model(s) to assess tumorgenic potential of cell substrates. Animal models will be developed to assess the tumorgenic potential of live cells themselves.

Part B: Develop, characterize and validate *in vitro* assays to assess and characterize tumorgenic potential of cell substrates. *In vitro* assays will be developed to assess the tumorgenic potential of live cells themselves. *In vitro* assays will also be developed to identify markers of cellular immortalization/transformation.

Part C: Develop, characterize and validate *in vivo* animal models to analyze the oncogenic potential of cellular DNA. Animal models will be developed to assess the risk of cell substrate DNA itself having oncogenic potential.

Part D: Develop, characterize and validate *in vitro* assays to analyze the oncogenic potential of cellular DNA. *In vitro* assays will be developed to assess the risk of cell substrate DNA itself having oncogenic potential.

Part E: Develop, characterize and validate assays for detection of novel or latent/occult adventitious agents in cell substrates. Assays will be developed to screen for infectious agents that are not detected by currently used adventitious agent tests. This will include development of assays to assess the potential for cell substrates to harbor and transmit TSEs.

Offerors may respond to any or all of Parts A, B, C, D, and E; however, a separate technical and business proposal must be submitted for each Part**.** Tasks encompassed under Parts B and D, including validation, must be completed within thirty-six (36) months from the date of award. Tasks encompassed under Parts A, C, and E, including validation, must be completed within sixty (60) months from the date of award.

Total available funding is $3,000,000 per year for all contracts awarded under this solicitation. It is anticipated that multiple contracts (2-5 contracts) will be awarded to successful Offerors demonstrating the capability of meeting the requirements of this solicitation. Negotiations will take place with Offerors for each of the lettered Parts. The government will sort all offerors by lettered Part and will create separate competitive ranges for each Part. If two or more Parts from a single offeror are in the competitive range, the government reserves the right to negotiate a single contract and the Offeror's Statement of Work will comprise all of the relevant Parts of the award**.**

Additional Information on the Scope and Requirements of this Solicitation

- Offerors may propose a single *in vivo* animal model, multiple *in vivo* animal models, a single *in vitro* assay or multiple *in vitro* assays for each Part of this solicitation. However, each proposed animal model and/or assay must be tested using two cell substrates.

- The development process for both *in vitro* assays and *in vivo* animal models will consist of two stages. The first stage will be to determine the general feasibility, utility and sensitivity of the *in vitro* assay and *in vivo* animal model. Upon completion of the first stage, the results will be analyzed, and those *in vitro* assays and *in vivo* animal models deemed promising by the government will be selected for validation – the second stage of development. Validation will be conducted in accordance with the most current U.S. Food and Drug Administration (FDA) and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines. Links to the most current information concerning validation can be found on the FDA website http://www.fda.gov/, and the ICH website http://www.ich.org/ich5.html.

- To the extent possible, efforts should focus on applying existing technologies, reagents, techniques, and animal strains to animal model development. For example, proposals to develop assays for *in* vitro analysis of the oncogenic potential of live cells could include a more thorough development and validation effort of the currently used growth in soft agar assay.

- The use of currently available animal strains, rather than the development of new animal strains (i.e., new knockout mice) is strongly encouraged. Furthermore, it is expected that the animals used in model development will be rodent models, such as mouse, rat or hamster. However, proposals to use other types of animals, either rodent of non-rodent, will be acceptable and considered.

Background

In 1954, the U.S. Armed Forces Epidemiology Board (AFEB) met to discuss the appropriate cell substrates to use for the manufacturing of an adenovirus vaccine. At the conclusion of these discussions, the AFEB recommended that "normal cells," rather than cell lines derived from tumors, be used as the cell substrates to manufacture an adenovirus vaccine. The reason for this decision was based in part on the concern that tumor-derived cells may be able to transfer occult oncogenic agents to vaccine recipients. The precedent set by the AFEB is still seen today, both in guidance documents from regulatory agencies and in the type of cell substrates used to manufacture vaccines. Indeed, all U.S. licensed viral vaccines are manufactured in one of three cell types: primary cells (e.g. chick-derived primary cells for making flu vaccine), diploid cells (i.e., MRC-5 for making chicken pox vaccine), and immortalized, non-tumorgenic cell lines (e.g., VERO for manufacturing inactivated polio virus). These types of cells have proven extremely successful in the manufacturing of viral vaccines, both in terms of safety and ability to produce large quantities of product. However, several recent advances in vaccine-related research have led to the development of vaccines that cannot be manufactured in these commonly used, well-defined cell substrates. For example, adenovirus-based vaccines require complementing cell lines that have been engineered to express the E1 adenovirus gene, rendering the cell line tumorgenic in immunosuppressed rodents.

As with more traditional vaccine cell substrates, it is critical that these new cell substrates be well characterized and undergo rigorous safety testing prior to their use in manufacturing vaccines for human use. One difficulty in characterizing and performing appropriate safety tests on these new cell substrates is that very few tests are available that were designed to specifically assay for characteristics that are unique to these new cells. For example, unlike traditional vaccine cell substrates, many of the new potential cell substrates can form tumors in certain immunosuppressed animal models. Unfortunately, no well-characterized assay is available to rigorously analyze this tumorgenic potential, such as assessing whether or not the tumorgenic potential changes as the cells are passaged, or if there is a threshold number of cells required to obtain the tumorgenic potential. As a result of the lack of specific assays, and the subsequent lack of data, it is very difficult for manufacturers and regulatory agencies to adequately assess the risk of vaccines produced in new cell substrates. In recent years, many powerful new technologies have been developed, including, but not limited to, novel PCR techniques, proteomic techniques, micro-array analysis, and more characterized animal models, which could be useful in the development of assays to screen for oncogenic potential and adventitious agents in novel cell substrates.

This RFP solicits proposals to develop *in vitro* assays and *in vivo* animal models that will allow a better assessment of the overall safety of vaccines and vaccine formulations, including a better understanding of the oncogenic potential of cell substrates, and better tools to screen for adventitious agents in these cell substrates. Once validated, these *in vitro* assays and *in vivo* animal models will provide an important tool for manufacturers to better characterize new cell substrates. This characterization will, in turn, allow manufacturers and regulatory agencies to more accurately assess risk, and analyze the safety of vaccines.

Statement of Work - PART A: *IN VIVO* ANIMAL MODELS TO ASSESS TUMEROGENIC POTENTIAL OF CELL SUBSTRATES

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

The Contractor shall be responsible for 1) developing one or more *in vivo* animal models to assess vaccine safety concerns such as the tumorgenic potential of live cellular substrates, or concerns that arise regarding vaccine formulations, including adjuvants or excipients, and, 2) if approved by the Project Officer, developing a validation plan and conducting studies to validate the *in vivo* animal models. Each *in vivo* animal model must be tested using two cell substrates. To the extent possible, efforts should focus on applying existing technologies, reagents, techniques, and animal strains to animal model development. Animal models that show promise during the first stage of development will be candidates for the second stage of development - validation. The tasks encompassed under Part A of this solicitation, including validation, must be completed within sixty (60) months from the date of award.

Specifically, the Contractor shall:

I. Develop, characterize, and validate *in vivo* animal model(s) to assess tumorgenic potential of live cell substrates.

1. During the first stage of development, characterize animal model(s) for the following:
    a. Sensitivity for detecting tumorgenic potential of live cells.
    b. Ability to detect changes in tumorgenic potential of cells lines as they are passaged.
    c. Sensitivity to dose-response (i.e., sensitivity to increasing doses of live cells).
    d. Sensitivity to different routes of inoculation.
    e. *In vivo* animal model development will include animal models currently used to assay for tumorgenic potential (i.e., nude mouse model) as a control arm. **See Notes 1, 3, 6, and 7 to Offeror**

2. Upon completion of the first stage of development, the NIAID Project Officer will determine if the assay will be a candidate for further development and validation. The decision process will consist of two steps. Immediately following completion of the assay development stage, the Project Officer and Contractor will meet to discuss the data, results, and conclusions from the development studies. If the Project Officer determines that sufficient information is available to warrant further development, the Contractor will be directed to prepare a concept validation plan. The concept validation plan will outline the studies to be performed to meet each of the assay validation criteria in accordance with the most current version of the ICH Q2A and Q2B documents. The Project Officer will then review the validation plan in consultation with the Contractor, the Advisory Committee (see section II below), regulatory agencies, and/or other experts as deemed necessary by the Project Officer, to determine if the assay validation plan is appropriate, and, if validated, whether the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. The final decision on whether or not the assay will be a candidate for validation will be based on the Project Officer's assessment that 1) the assay can be validated; and 2) if validated, the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. Following selection of an animal model for validation, the Contractor will plan, prepare and conduct validation of the animal model. This will include:
    a. Develop a detailed validation plan. Validation must be performed in accordance with the most current version of the ICH Q2A and Q2B documents. As indicated in ICH Q2A, validation characteristics should include: Accuracy, Precision, Specificity, Detection Limit, Quantitation Limit, Linearity, and Range. The validation plan will include the following information/sections: Cover page, table of contents, purpose, study objective, responsibilities, definitions, summary of completed studies, study description, sample description, materials and supplies, equipment information, test methods, Standard Operating Procedures (SOPs), test protocol (Test functions describing each validation parameter, how it will be tested, and the acceptance criteria), data handling and analysis, and report requirements.
    b. Conduct validation studies according to validation plan.
    c. Perform data analysis at the conclusion of the validation studies.

d. Prepare study report. Report will include the following sections/information: Cover page, table of contents, abstract, methods and materials, results, conclusions, and appendices. The 'results' section of the study report will be divided into subsections, with each subsection dedicated to one of the validation parameters (based on the test protocol). **See Note 4 to Offeror**

II. PARTICIPATE IN ADVISORY COMMITTEE ACTIVITIES

The NIAID Project Officer will form an Advisory Committee to provide expert advice on certain issues related to the ongoing work performed under this contract. The input and advice provided by the Advisory Committee, in conjunction with input from regulatory agencies and the Contractor, will be used by the Project Officer to aid in making decisions regarding animal model development and animal model validation. The Project Officer will determine the composition and number of members of the Advisory Committee. Members may be added or removed as necessary to meet the needs of the Government. Two-day Advisory Committee meetings will be held twice each year of the contract in the Bethesda, MD area. The Contractor will participate in these meetings to support the Advisory Committee as requested by the Project Officer. Participation will include presenting and discussing test results, and providing expert opinions on methodologies and animal model development and validation. The Contractor will also provide additional support for Advisory Committee meetings, including: providing read ahead documents prior to Advisory Committee meetings; scheduling and making all logistical arrangements for Committee meetings; and supporting the travel of two (2) non-Federal Committee members. **See Note 8 to Offeror**

III. PROVIDE FOR AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR OR THE GOVERNMENT ON OR BEFORE THE COMPLETION DATE OF THIS CONTRACT

Twelve months prior to the completion date of this contract, a transition plan, which will include access to all data, shall be submitted to the NIAID Project Officer for review and approval, in order to ensure orderly transition of contract-related material to a successor contractor or the Government. The transition plan will include a detailed description of the methods and procedures for the transition, the timeline for preparation and delivery of various materials, and the mechanism(s) to be used to provide access to all data generated under this contract. **See Note 9 to Offeror**

Statement of Work - PART B: *IN VITRO* ASSAYS TO ASSESS TUMEROGENIC POTENTIAL OF CELL SUBSTRATES

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

The Contractor will be responsible for 1) developing one or more *in vitro* assays to assess vaccine safety concerns such as characterization of the tumorgenic potential of live cellular substrates, or concerns that arise regarding vaccine formulations, including adjutants or excipients, and 2) if approved by the Project Officer, developing a validation plan and conducting studies to validate the *in vitro* assay(s). Each *in* vitro assay must be tested using two cell substrates. To the extent possible, efforts should focus on applying existing technologies-y, reagents, and techniques, to the *in vitro* assay development. *In vitro* assays that show promise during the first stage of development will be candidates for the second stage of development-validation. The tasks encompassed under Part B of this solicitation, including validation, must be completed within thirty-six (36) months from the date of award.

Specifically, the Contractor shall:

I. Develop, characterize and validate *in vitro* assays to assess and characterize tumorgenic potential of cell substrates.

1. During the first stage of development, characterize *in vitro* assays to assess tumorgenic potential of cell substrates, including:
    a. Sensitivity for detecting tumorgenic potential of live cell substrates.
    b. Ability to detect changes in tumorgenic potential of cells lines as they are passaged.
    c. Sensitivity to dose response (i.e. Sensitivity to increasing doses of live cells).
    d. Development of *in vitro* assays will include *in vitro* assays currently used to comparison studies with *in vitro* assays currently used to assay for tumorgenic potential (i.e. colony formation in soft agar).
2. During the first stage of development, characterize *in vitro* assays to identify cellular markers and/or other patterns that correlate with changes in tumorgenic potential of cell substrates (e.g., the use of microarray analysis to compare gene expression in early passage Vero cells, which are non-tumorgenic, with late passage Vero Cells, which are capable of forming tumors in some animal models).
3. During the first stage of development, characterize *in vitro* methods to reverse tumorgenic affect in cells that have been immortalized/transformed by a known mechanism (e.g., express the adenovirus E1 gene in cells, and determine if subsequent inhibition of E1 protein expression causes the cell to lose its tumorgenic phenotype. Mechanisms used to inhibit E1 protein expression could include expressing E1 from an inducible promoter, or using anti-sense technology). **See Notes 2, 3, 6, and 7 to Offeror**

4. Upon completion of the first stage of development, the NIAID Project Officer will determine if the assay will be a candidate for further development and validation. The decision process will consist of two steps. Immediately following completion of the assay development stage, the Project Officer and Contractor will meet to discuss the data, results, and conclusions from the development studies. If the Project Officer determines that sufficient information is available to warrant further development, the Contractor will be directed to prepare a concept validation plan. The concept validation plan will outline the studies to be performed to meet each of the assay validation criteria in accordance with the most current version of the ICH Q2A and Q2B documents. The Project Officer will then review the validation plan in consultation with the Contractor, the Advisory Committee (see section II below), regulatory agencies, and/or other experts as deemed necessary by the Project Officer, to determine if the assay validation plan is appropriate, and, if validated, whether the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. The final decision on whether or not the assay will be a candidate for validation will be based on the Project Officer's assessment that 1) the assay can be validated; and 2) if validated, the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. Following selection of an assay for validation, the Contractor will plan, prepare and conduct validation of the *in vitro* assay. This will include:
    a. Develop a detailed validation plan. Validation must be performed in accordance with the most current version of the ICH Q2A and Q2B documents. As indicated in ICH Q2A, validation characteristics should include: Accuracy, Precision, Specificity, Detection Limit, Quantitation Limit, Linearity, and Range. The validation plan will include the following

information/sections: Cover page, table of contents, purpose, study objective, responsibilities, definitions, summary of completed studies, study description, sample description, materials and supplies, equipment information, test methods, Standard Operating Procedures (SOPs), test protocol (Test functions describing each validation parameter, how it will be tested, and the acceptance criteria), data handling and analysis, and report requirements.

b. Conduct validation studies according to validation plan.
c. Perform data analysis at the conclusion of the validation studies.
d. Prepare study report. Report will include the following sections/information: Cover page, table of contents, abstract, methods and materials, results, conclusions, and appendices. The 'results' section of the study report will be divided into subsections, with each subsection dedicated to one of the validation parameters (based on the test protocol). **See Note 5 to Offeror**

II. PARTICIPATE IN ADVISORY COMMITTEE ACTIVITIES

The NIAID Project Officer will form an Advisory Committee to provide expert advice on certain issues related to the ongoing work performed under this contract. The input and advice provided by the Advisory Committee, in conjunction with input from regulatory agencies and the Contractor, will be used by the Project Officer to aid in making decisions regarding assay development and assay validation. The Project Officer will determine the composition and number of members of the Advisory Committee. Members may be added or removed as necessary to meet the requirements of the Government. Two-day Advisory Committee meetings will be held twice each year of the contract in the Bethesda, MD area. The Contractor will participate in these meetings to support the Committee as requested by the Project Officer. Participation will include presenting and discussing test results, and providing expert opinions on methodologies and assay development and validation. The Contractor will also provide additional support for the Advisory Committee meetings, including providing read ahead documents prior to a committee meeting; scheduling and making all logistical arrangements for Committee meetings; and supporting the travel of two non-Federal Committee members. **See Note 8 to Offeror**

III. PROVIDE FOR AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR OR THE GOVERNMENT ON OR BEFORE THE COMPLETION DATE OF THIS CONTRACT

Twelve months prior to the completion date of this contract, a transition plan, which will include access to all data, shall be submitted to the NIAID Project Officer for review and approval, in order to ensure orderly transition of contract-related material to a successor contractor or the Government. The transition plan will include a detailed description of the methods and procedures for the transition, the timeline for preparation and delivery of various materials, and the mechanism(s) to be used to provide access to all data generated under this contract. **See Note 9 to Offeror**

Statement of Work - PART C: *IN VIVO* ANIMAL MODELS TO ASSESS ONCOGENIC POTENTIAL OF CELLULAR DNA

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

The Contractor shall be responsible for 1) developing one or more animal models to assess the oncogenic potential of the DNA of cellular substrates, and 2) if approved by the Project Officer, developing a validation plan and conducting studies to validate the *in vivo* animal models. Each *in vivo* animal model must be tested using two cell substrates. To the extent possible, efforts should focus on applying existing technologies, reagents, techniques, and animal strains to the animal model development. Animal models that show promise during the first stage of development will be candidates for the second stage of development, validation. The tasks encompassed under Part C of this solicitation must be completed within sixty (60) months from the date of award.

Specifically, the Contractor shall:

I. Develop, characterize and validate *in vivo* animal models to analyze the oncogenic potential of cellular DNA.

1. During the first stage of development, examine both purified cellular DNA and purified cleaved cellular DNA in the *in vivo* animal models. The purpose of using the cleaved DNA is to mimic the fragmented cellular DNA that is often found in supernatants of viral products produced in cellular substrates. Parameters to be tested include: dose, route of inoculation, and incubation period. **See Notes 1, 3, 6, and 7 to Offeror**

2. Upon completion of the first stage of development, the NIAID Project Officer will determine if the animal model(s) will be a candidate for further development and validation. The decision process will consist of two steps. Immediately following completion of the animal model development stage, the Project Officer and Contractor will meet to discuss the data, results, and conclusions from the development studies. If the Project Officer determines that sufficient information is available to warrant further development, the Contractor will be directed to prepare a concept validation plan. The concept validation plan will outline the studies to be performed to meet each of the assay validation criteria in accordance with the most current version of the ICH Q2A and Q2B documents. The Project Officer will then review the validation plan in consultation with the Contractor, the Advisory Committee (see section II below), regulatory agencies, and/or other experts as deemed necessary by the Project Officer, to determine if the assay validation plan is appropriate, and, if validated, whether the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. The final decision on whether or not the assay will be a candidate for validation will be based on the Project Officer's assessment that 1) the assay can be validated; and 2) if validated, the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. Following selection of an animal model for validation, the contractor will plan, prepare and conduct validation of the animal model. This will include:
    a. Develop a detailed validation plan. Validation must be performed in accordance with the most current version of the ICH Q2A and Q2B documents. As indicated in ICH Q2A, validation characteristics should include: Accuracy, Precision, Specificity, Detection Limit, Quantitation Limit, Linearity, and Range. The validation plan will include the following information/sections: Cover page, table of contents, purpose, study objective, responsibilities, definitions, summary of completed studies, study description, sample description, materials and supplies, equipment information, test methods, Standard Operating Procedures (SOPs), test protocol (Test functions describing each validation parameter, how it will be tested, and the acceptance criteria), data handling and analysis, and report requirements.
    b. Conduct validation studies according to validation plan.
    c. Perform data analysis at the conclusion of the validation studies.
    d. Prepare study report. Report will include the following sections/information: Cover page, table of contents, abstract, methods and materials, results, conclusions, and appendices. The 'results' section of the study report will be divided into subsections, with each subsection dedicated to one of the validation parameters (based on the test protocol). **See Note 4 to Offeror**

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The NIAID Project Officer will form an Advisory Committee to provide expert advice on certain issues related to the ongoing work performed under this contract. The input and advice provided by the Advisory Committee, in conjunction with input from regulatory agencies and the Contractor, will be used by the Project Officer to aid in making decisions regarding animal model development and animal model validation. The Project Officer will determine the composition and number of members of the Advisory Committee. Members may be added or removed as necessary to meet the requirements of the Government. Two-day Advisory Committee meetings will be held twice each year of the contract in the Bethesda, MD area. The Contractor will participate in these meetings and/or teleconferences to support the Advisory Committee. Participation will include presenting and discussing test results, and providing expert opinions on methodologies and animal model development and validation. The Contractor will also provide additional support for Advisory Committee activities, including providing read ahead documents prior to a committee meeting; scheduling and making all logistical arrangements for Committee meetings; and support the travel of two (2) non-Federal Committee members. **See Note 8 to Offeror**

III. PROVIDE FOR AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR OR THE GOVERNMENT ON OR BEFORE THE COMPLETION DATE OF THIS CONTRACT

Twelve months prior to the completion date of this contract, a transition plan, which will include access to all data, shall be submitted to the NIAID Project Officer for review and approval, in order to ensure orderly transition of contract-related material to a successor contractor or the Government. The transition plan will include a detailed description of the methods and procedures for the transition, the timeline for preparation and delivery of various materials, and the mechanism(s) to be used to provide access to all data generated under this contract. **See Note 9 to Offeror**

Statement of Work - PART D: *IN VITRO* ASSAYS TO ANALYZE THE ONCOGENIC POTENTIAL OF CELLULAR DNA

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

The Contractor will be responsible for 1) developing one or more *in vitro* assays to assess the oncogenic potential of the DNA of cellular substrates, and 2) if approved by the Project Officer, developing a validation plan and conducting studies to validate the *in vitro* assay(s). Each *in* vitro assay must be tested using two cell substrates. To the extent possible, efforts should focus on applying existing technologies, reagents, and techniques, to the *in vitro* assay development. Assays that show promise during the first stage of development will be candidates for the second stage of development, validation. The tasks encompassed under Part D of this solicitation, including validation, must be completed within thirty-six (36) months from the date of award.

Specifically, the contractor shall:

I. Develop, characterize and validate *in vitro* assays to analyze the oncogenic potential of cellular DNA.

1. During the first stage of development, examine both purified cellular DNA and cleaved cellular DNA in the *in vitro* assay. The purpose of using the cleaved DNA is to mimic the fragmented cellular DNA that is often found in supernatants of viral products produced in cellular substrates. Parameters to be tested include: dose and incubation period. **See Notes 2, 3, 6, and 7 to Offeror**

2. Upon completion of the first stage of development, the NIAID Project Officer will determine if the assay will be a candidate for further development and validation. The decision process will consist of two steps. Immediately following completion of the assay development stage, the NIAID Project Officer and Contractor will meet to discuss the data, results, and conclusions from the development studies. If the Project Officer determines that sufficient information is available to warrant further development, the Contractor will be directed to prepare a concept validation plan. The concept validation plan will outline the studies to be performed to meet each of the assay validation criteria in accordance with the most current version of the ICH Q2A and Q2B documents. The Project Officer will then review the validation plan in consultation with the Contractor, the Advisory Committee (see section II below), regulatory agencies, and/or other experts as deemed necessary by the Project Officer, to determine if the assay validation plan is appropriate, and, if validated, whether the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. The final decision on whether or not the assay will be a candidate for validation will be based on the Project Officer's assessment that 1) the assay can be validated; and 2) if validated, the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. Following selection of an animal model for validation, the Contractor will plan, prepare and conduct validation of the animal model. This will include:
    a. Develop a detailed validation plan. Validation must be performed in accordance with the most current version of the ICH Q2A and Q2B documents. As indicated in ICH Q2A, validation characteristics should include: Accuracy, Precision, Specificity, Detection Limit, Quantitation Limit, Linearity, and Range. The validation plan will include the following information/sections: Cover page, table of contents, purpose, study objective, responsibilities, definitions, summary of completed studies, study description, sample description, materials and supplies, equipment information, test methods, Standard Operating Procedures (SOPs), test protocol (Test functions describing each validation parameter, how it will be tested, and the acceptance criteria), data handling and analysis, and report requirements.
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    c. Perform data analysis at the conclusion of the validation studies.
    d. Prepare study report. Report will include the following sections/information: Cover page, table of contents, abstract, methods and materials, results, conclusions, and appendices. The 'results' section of the study report will be divided into subsections, with each subsection dedicated to one of the validation parameters (based on the test protocol). **See Note 5 to Offeror**

II. PARTICIPATE IN ADVISORY COMMITTEE ACTIVITIES

The NIAID Project Officer will form an Advisory Committee to provide expert advice on certain issues related to the ongoing work performed under this contract. The input and advice provided by the committee, in conjunction with input from regulatory agencies and the Contractor, will be used by the Project Officer to aid in making decisions regarding *in vitro* assay development and *in vitro* assay validation. The Project Officer will determine the composition and number of members of the Advisory Committee. Members may be added or removed as necessary to meet the needs of the Government. Two-day Advisory Committee meetings will be held twice each year of the contract in the Bethesda, MD area. The Contractor will participate in these meetings to support the Advisory Committee as requested by the Project Officer. Participation will include presenting and discussing test results, and providing expert opinions on methodologies and *in vitro* assay development and validation. The Contractor will also provide additional support for Advisory Committee activities, including providing read ahead documents prior to a committee meeting; scheduling and making all logistical arrangements for Committee meetings; and support the travel of two (2) non-Federal Committee members. **See Note 8 to Offeror**

III. PROVIDE FOR AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR OR THE GOVERNMENT ON OR BEFORE THE COMPLETION DATE OF THIS CONTRACT

Twelve months prior to the completion date of this contract, a transition plan, which will include access to all data, shall be submitted to the NIAID Project Officer for review and approval, in order to ensure orderly transition of contract-related material to a successor contractor or the Government. The transition plan will include a detailed description of the methods and procedures for the transition, the timeline for preparation and delivery of various materials, and the mechanism(s) to be used to provide access to all data generated under this contract. **See Note 9 to Offeror**

Statement of Work - PART E: ASSAYS FOR DETECTION OF NOVEL OR LATENT/OCCULT ADVENTITIOUS AGENTS IN CELL SUBSTRATES

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

The Contractor shall be responsible for 1) developing one or more assays to identify latent and/or occult adventitious agents present in cell substrates, and 2) if approved by the Project Officer, developing a validation plan and conducting studies to validate the assay(s). Each assay must be tested using two cell substrates. To the extent possible, efforts should focus on applying existing technologies, reagents, techniques, and animal strains to the assay development. Assays that show promise during the first stage of development will be candidates for the second stage of development, validation. The tasks encompassed under Part E of this solicitation must be completed within sixty (60) months from the date of award.

Specifically, the Contractor shall:

I. Develop, characterize and validate assays for the detection of novel or latent/occult adventitious agents in cell substrates. Assays can include *in vitro* assays, *in vivo* animal models, and/or assays that contain both an *in vitro* assay and an *in vivo* animal model component.

1. During the first stage of development, characterize assays that can be used to screen for unidentified latent adventitious agents. Examples of potential assays to be developed include:
    a. Assays to identify cellular genes that are normally inactivated but become specifically activated in the presence of a wide range of infectious agents.
    b. Development of degenerative primers for either microarray or PCR analysis to screen for previously unidentified viruses that are related to known viruses.
    c. Use of chemical stimulants to activate latent viruses in the cell substrate. Stimulation could be coupled with a non-specific detection system, such as PERT or TEM to look for activated viruses.
    d. Using whole cell lysate in *in vitro* assays and in animal models to determine if virus is released from latency or otherwise activated following cell lysis.
2. During the first stage of development, characterize sensitive methods to screen for TSE agents in cell substrates. Examples of potential assays to be developed include:
    a. Screening for TSE infection and ability to propagate TSE in cells exposed to BSE contaminated serum.
    b. Assays to determine if cell substrates are producing the variant form of the PrP protein.

For offerors who propose to develop animal models, see Notes 1, 3, 6, and 7to Offeror
For offerors who propose to develop *in vitro* assays, see Notes 2, 3, 6, and 7 to Offeror

3. Upon completion of the first stage of development, the NIAID Project Officer will determine if the assay will be a candidate for further development and validation. The decision process will consist of two steps. Immediately following completion of the assay development stage, the NIAID Project Officer and Contractor will meet to discuss the data, results, and conclusions from the development studies. If the Project Officer determines that sufficient information is available to warrant further development, the Contractor will be directed to prepare a concept validation plan. The concept validation plan will outline the studies to be performed to meet each of the assay validation criteria in accordance with the most current version of the ICH Q2A and Q2B documents. The Project Officer will then review the validation plan in consultation with the Contractor, the Advisory Committee (see section II below), regulatory agencies, and/or other experts as deemed necessary by the Project Officer, to determine if the assay validation plan is appropriate, and, if validated, whether the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. The final decision on whether or not the assay will be a candidate for validation will be based on the Project Officer's assessment that 1) the assay can be validated; and 2) if validated, the assay will provide meaningful, relevant information for regulatory agencies and vaccine manufacturers to better characterize novel cell substrates. Following selection of an animal model for validation, the Contractor will plan, prepare and conduct validation of the animal model. This will include:

a. Develop a detailed validation plan. Validation must be performed in accordance with the most current version of the ICH Q2A and Q2B documents. As indicated in ICH Q2A, validation characteristics should include: Accuracy, Precision, Specificity, Detection Limit, Quantitation Limit, Linearity, and Range. The validation plan will include the following information/sections: Cover page, table of contents, purpose, study objective, responsibilities, definitions, summary of completed studies, study description, sample description, materials and supplies, equipment information, test methods, Standard Operating Procedures (SOPs), test protocol (Test functions describing each validation parameter, how it will be tested, and the acceptance criteria), data handling and analysis, and report requirements.
b. Conduct validation studies according to validation plan.
c. Perform data analysis at the conclusion of the validation studies.
d. Prepare study report. Report will include the following sections/information: Cover page, table of contents, abstract, methods and materials, results, conclusions, and appendices. The 'results' section of the study report will be divided into subsections, with each subsection dedicated to one of the validation parameters (based on the test protocol).

For offerors who propose to develop *in vivo* animal models, see Note 4 to Offeror
For offerors who propose to develop *in vitro* assays, see Note 5 to Offeror

II. PARTICIPATE IN ADVISORY COMMITTEE ACTIVITIES

The NIAID Project Officer will form an Advisory Committee to provide expert advice on certain issues related to the ongoing work performed under this contract. The input and advice provided by the Advisory Committee, in conjunction with input from regulatory agencies and the Contractor, will be used by the Project Officer to aid in making decisions regarding assay development and assay validation. The Project Officer will determine the composition and number of members of the Advisory Committee. Members may be added or removed as necessary to meet the needs of the Government. Two-day Advisory Committee meetings will be held twice each year of the contract in the Bethesda, MD area. The Contractor will participate in these meetings to support the Advisory Committee as requested by the Project Officer. Participation will include presenting and discussing test results, and providing expert opinions on methodologies and assay development and validation. The Contractor will also provide additional support for Advisory Committee activities, including providing read ahead documents prior to a committee meeting; scheduling and making all logistical arrangements for Committee meetings; and support the travel of two (2) non-Federal Committee members. **See Note 8 to Offeror**

III. PROVIDE FOR AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR OR THE GOVERNMENT ON OR BEFORE THE COMPLETION DATE OF THIS CONTRACT

Twelve months prior to the completion date of this contract, a transition plan, which will include access to all data, shall be submitted to the NIAID Project Officer for review and approval, in order to ensure orderly transition of contract-related material to a successor contractor or the Government. The transition plan will include a detailed description of the methods and procedures for the transition, the timeline for preparation and delivery of various materials, and the mechanism(s) to be used to provide access to all data generated under this contract. **See Note 9 to Offeror**

NOTES TO OFFEROR

Assessing Safety of Cell Substrates and Vaccine Components

NOTE ONE (1) TO OFFEROR:

Technical proposals must include:

A. Detailed description of the methodologies and techniques that will be utilized to perform the proposed tasks.
B. For *in vivo* animal model development:
    i. To the extent possible, offerors shall include a development path, including timelines, for each proposed *in vivo* animal model
    ii. Each proposed animal model will include a section discussing the rationale for animal selection and overall study design, including a development plan synopsis which describes the initial series of experiments (including number of animals, dose, route, and incubation periods) that would be performed as part of *in vivo* animal model development.

NOTE TWO (2) TO OFFEROR:

Technical proposals must include:

A. A detailed description of the methodologies and techniques that will be utilized to perform the proposed tasks.
B. To the extent possible, offerors shall include a development path, including timelines, for each proposed *in vitro* assay.
C. Each proposed *in vitro* assay will include a section discussing the rationale for overall study design, including a development plan synopsis which describes the initial experiments (including sample preparation, amount of sample to be tested, and incubation periods) that would be performed as part of the initial assay development.

NOTE THREE (3) TO OFFEROR:

For each proposed *in vitro* assay or *in vivo* animal model, offerors should propose to perform the development and characterization work on two (2) different cell substrates. The Project Officer will determine the cell substrates that are to be used for assay development.

NOTE FOUR (4) TO OFFEROR:

For *in vivo* animal model validation:

A. Animal model validation will include completing all validation studies on two (2) separate cell substrates. The Project Officer will determine the cell substrates that are to be used for assay validation.
B. Assay validation will include assessment of inter-laboratory variability. Offerors should describe how they will assess inter-laboratory variability.
C. Proposals must include a study protocol for validation of one proposed animal model. Protocol must also include a plan for assessing inter-laboratory variability.

NOTE FIVE (5) TO OFFEROR:

For *in vitro* assay validation:

A. *In vitro* assay validation will include completing all validation studies on two (2) separate cell substrates. The Project Officer will determine the cell substrates that are to be used for assay validation.
B. *In vitro* assay validation will include assessment of inter-laboratory variability. Offerors should describe how they will assess inter-laboratory variability.
C. Proposals must include a study protocol for validation of one proposed *in vitro* assay. Protocol must also include a plan for assessing inter-laboratory variability.

NOTE SIX (6) TO OFFEROR:

If development of more than one *in vitro* assay or *in vivo* animal model is proposed for a single part, the corresponding business proposal must have a separate cost breakdown for each proposed *in vitro* assay or *in vivo* animal model

NOTE SEVEN (7) TO OFFEROR

The business proposal for each proposed *in vitro* assay and *in vivo* animal model must be separated into two distinct, stand-alone sections, the first section detailing the cost for development of the *in vitro* assay or *in vivo* animal model, and the second section detailing the cost for validation of the *in vitro* assay or *in vivo* animal model.

NOTE EIGHT (8) TO OFFEROR:

For cost estimating purposes, assume that two (2) individuals from the contractor site will be required to travel to Bethesda, MD twice a year for meetings with the Project Officer.

NOTE NINE (9) TO OFFEROR

Proposals must include a brief description of the transition plan, including the mechanism by which the Project Officer will be given access to all data generated under this contract.

REPORTING REQUIREMENTS

Assessing Safety of Cell Substrates and Vaccine Components

As part of the work to be performed under this contract, the Contractor shall prepare and deliver the following reports throughout the period of work. The Contractor shall submit electronic and hard copy versions of each report. The exact submission schedule will be negotiated and established in the contract document.

All reports shall submitted shall contain a title page that includes:

Contract number and title
Contract Project Officer
Type of report (Quarterly, Annual, or Final)
Period of performance being reported
Contractor's name and address
Author(s)
Date of Submission

I. SEMI-ANNUAL TECHNICAL PROGRESS REPORT

By the fifteenth working day of the month following the end of each six month period, the Contractor shall submit three (3) copies of a semi-annual Technical Progress Report, comprising two (2) copies [one (1) hard copy and one (1) electronic copy] to the Project Officer and one (1) hard copy to the Contracting Officer. The semi-Annual Report shall be factual and concise and consist of the following:

a. Section I: An introduction covering the purpose and scope of the contract effort.

b. Section II: Brief overview of all work performed on development and validation in the previous six months.

c. Section III: Description of overall progress, plus a separate description for each task or segment of work on which effort was expended during the reporting period. The description for each task will include:

   i. Pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;
   ii. Any scientific, technical, or other problems/difficulties encountered;
   iii. Brief description of planned work for the following six month period;
   iv. Any recommendations for the modification, expansion, curtailment and/or termination of development/validation of the assay.

d. Section IV: An anticipated work plan for the following six moths.

e. Section V: A description of all impediments in carrying out the work tasks, whether affecting performance or costs, and methods implemented to overcome impediments. If impediments are ongoing, report should include recommendations for their resolutions.

f. Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.

II. ANNUAL REPORT

On the anniversary date of the contract, the Contractor shall submit three (3) copies of an Annual Technical Progress Report, as above, comprising two (2) copies to the Project Officer [one (1) hard copy and one (1) electronic copy] and one (1) hard copy to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire contact work for the period covered.

a. Section I: An introduction covering the purpose and scope of the contract effort.

b. Section II: Brief overview of all work performed since the last annual report, including progress on meeting objectives identified in the previous annual report.

c. Section III: Description of overall progress, plus a separate description for each task or segment of work on which effort was expended during the report period. The description for each task will include:

   i. Pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;
   ii. Any scientific, technical, or other problems/difficulties encountered;
   iii. Brief description of planned work for the following six month period;
   iv. Any recommendations for the modification, expansion, curtailment and/or termination of development/validation of the assay.

d. Section IV: Objectives for the upcoming 12-month period, and an anticipated work plan that will allow the objectives to be met.

e. Section V: A description of all impediments in carrying out the work tasks, whether affecting performance or costs, and methods implemented to overcome impediments. If impediments are ongoing, report should include recommendations for their resolutions.

f. An annual report will not be required for the period when the final report is due.

III. FINAL REPORT

At the completion of the contract period, the Contractor shall submit the Final Technical Report summarizing the results for the entire contract work for the complete performance period. A draft of the Final Report shall be submitted 30-days prior to the expiration date of the contract. Project Officer will have 14-days from date of receipt to review and comment on the draft final report. The Final Report shall be submitted by the expiration date of the contract and shall be submitted in place of the last Annual Report. The Contractor shall submit three (3) copies of the Final Report, comprising two (2) copies to the Project Officer [one (1) hard copy and one (1) electronic copy] and one (1) hard copy to the Contracting Officer.

The Final Report shall include:

a. A detailed description of the results of all work conducted under this contract. Description should be in sufficient detail to explain comprehensively the results achieved.

b. Conclusions regarding work performed and recommendations for continued development of assays.

c. Recommendations for new assays/approaches that could be investigated to achieve the aims laid out in this RFP.

d. Final cost of work performed on each assay.

e. A discussion of problems and obstacles encountered while performing assay development and validation. Discussion should include both technical and programmatic issues, and should detail methods (both successful and unsuccessful) that were used to overcome the problems and obstacles, and recommendations for improvements.

IV. OTHER DELIVERABLES

1. Draft assay development protocols will be delivered to the project officer for review and approval at least 30 days prior to planned study initiation. Final assay development protocols will be delivered to the project officer at least 7 days prior to planned study initiation.
2. Draft assay validation plans will be delivered to the project officer for review and approval at least 45 days prior to planned study initiation. Validation plans will include the following information/sections: Cover page, table of contents, purpose, study objective, responsibilities, definitions, summary of completed studies, study description, sample description, materials and supplies, equipment information, test methods, Standard Operating Procedures

(SOPs), test protocol (Test functions describing each validation parameter, how it will be tested, and the acceptance criteria), data handling and analysis, and report requirements. Final assay validation protocols will be delivered to the project officer at least 7 days prior to planned study initiation.

3. Draft and Final study reports for all implemented studies, including assay development, assay validation, and assays that were terminated/curtailed prior to completion of assay development or assay validation. Draft reports are due 60 days following completion of validation studies, or termination/curtailment of studies. Report will include the following sections/information: Cover page, table of contents, abstract, methods and materials, results (which will include data analysis and compilation of data into figures and/or tables as requested by the NIAID Project Officer), conclusions, and appendices. For assay validation study reports, the 'results' section of the study report will be divided into subsections, with each subsection dedicated to one of the validation parameters (based on the test protocol). Final reports are due 30 days after the contractor has received comments from the NIAD Project Officer.
4. Contractor shall provide reports as indicated under Reporting Requirements.
5. Contractor shall provide data, reports, and other information related to this Contract as requested by the Project Officer.

Six months prior to the completion date of this contract, a transition plan shall be submitted by the contactor to the NIAID Project Officer for review and approval. The transition plan will be a detailed plan for the orderly transition of contract-related material to a successor contractor or the government. The transition plan will include a detailed description of the methods and procedures for the transition, the timeline for preparation and delivery of various materials, and the mechanism(s) to be used to provide access to all data generated under this contract.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

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

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

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this URL: http://www.arnet.gov/far/.

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

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000), Alternate II (Apr 1998)
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan, Alternate I (Oct 2000)
52.219-14	Dec 1996	Limitations on Subcontracting
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.223-6	May 2001	Drug-Free Workplace
52.227-14	Jun 1987	Rights in Data – General
52.227-14	Jun 1987	Rights in Data - General, Alternate IV (Jun 1987)
52.232-1	Apr 1984	Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.243-2	Aug 1987	Changes - Cost Reimbursement
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate I (Apr 1984)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)

52.244-2	Aug 1998	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in Article B, Advance Understandings.
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-6	Sep 1996	Termination (Cost-Reimbursement), Alternate IV (Sep 1996)

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

HHSAR Clause No.	Date	Title
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

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

FAR 52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (OCTOBER 1999).

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

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

HHSAR 352.223-70, Safety and Health (JANUARY 2001) [This clause is provided in full text in SECTION J - ATTACHMENTS.]

HHSAR 352.224-70, Confidentiality of Information (APRIL 1984).

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

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

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

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

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

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

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

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: February 3, 2004] (Attached to this listing)

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

RFP FORMS AND ATTACHMENTS:

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

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

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

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Government Notice for Handling Proposals**

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

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan Format *[if applicable]***
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-1: Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH-2706: Financial Report of Individual Project Contract**
- **Instructions for Completing Form NIH-2706**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule - TBD**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals. *You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

ELECTRONIC SUBMISSION: *In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical. The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.*

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

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

"RFP NO. NIH-NIAID-DMID-04-22
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

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

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Robert Singman Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Robert Singman Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 175 PAGES, PER PART, EXCLUDING THE SAMPLE ASSAY VALIDATION PROTOCOL. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. THIS PAGE LIMIT INCLUDES ANY OF THE FOLLOWING ITEMS: (Offerors shall provide ten [10] copies of any non-electronic documentation with their original technical proposal.) Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Documents must be converted to a .pdf searchable format.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT RESPONSE SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist via e-mail.
3. Log-in Password: Will be provided by the Contract Specialist via e-mail.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-04-22
RFP Title: Assessing Safety of Cell Substrates and Vaccine Components

Please review the attached Request for Proposal. Furnish the information requested below and return this page by February 3, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

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

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Robert Singman
RFP-NIH-NIAID-DMID-04-22
FAX# (301) 496-0972
Email : rsingman@niaid.nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

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

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

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

(ii) (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).

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

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular

circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

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

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

b. **NAICS CODE AND SIZE STANDARD**

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

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

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

It is anticipated that MULTIPLE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about September 30, 2004.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF three to five (3-5) 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 42,536 hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

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 the Project Officer or 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 is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

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 General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Paul D. McFarlane
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA, MD 20892-7612

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

(End of Provision)

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 addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J, hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

a. Project Objectives, NIH-1688-1

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

- **For an Institution of Higher Education: The form <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, "<u>INSTRUCTIONS</u>:"

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS.) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(8) **Care of Live Vertebrate Animals**

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

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

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

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

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

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

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

(9) **Possession, Use and Transfer of Select Biological Agents or Toxins**

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins:

Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety)**; Agricultural Bioterrorism Protection Act of 2002,** which consists of **7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to plant health or plant products)**; and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to human and animal health, animal health or animal products) - **December 13, 2002**

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the USA Patriot Act. They are designed to improve the United States Government's ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Unless exempted, entities must receive a certificate of registration or be authorized to work with the applicable select agents as follows:

For possession, use and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to: 1) public health and safety; 2) both human and animal health, animal health, or animal products; and/or 3) plant health or plant products, registration information must be submitted to the Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA) as applicable.

Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

(10) **Obtaining and Disseminating Biomedical Research Resources**

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

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

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

(11) **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 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

**Note to Offeror: If this RFP is for a Multi-Center Clinical Trial or Epidemiological Study, the following paragraph will also apply.*

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.

(12) **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.

(13) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

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

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

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

While it is this Institute’s policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual

terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the FedBizOpps.

(14) **Small Business Subcontracting Plan**

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

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

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

(15) **Extent of Small Disadvantaged Business Participation**

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

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

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

(16) **Salary Rate Limitation in Fiscal Year 2003**

NOTE: This award is intended to be made in Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/PAYRATES/index.htm>
(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).

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

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
b) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

(18) **Prohibition on Contractor Involvement with Terrorist Activities**

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

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

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

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) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

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

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

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) Information Other than Cost or Pricing Data

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

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

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

(3) Cost and Pricing Data

1. **General Instructions**

A. You must provide the following information 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 of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced 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.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The

Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **NIH-2043, Proposal Summary and Data Record** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing

data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

(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)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Qualifications of the Offeror

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

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

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

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the

Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

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

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

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be

obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

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

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

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

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

(7) Subcontractors

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

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

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

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

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

(8) Proposer's Annual Financial Report

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

(9) 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.

(10) 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.

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

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

(12) Guidance Regarding Federal Government Collaborations

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price 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.

There are five separate parts covered under this RFP, each focusing on a specific area of *in vitro* assay development or *in vivo* animal model development: **Part A: Develop, characterize and validate *in vivo* animal model(s) to assess tumorgenic potential of cell substrates.** Animal models will be developed to assess the tumorgenic potential of live cells themselves. **Part B: Develop, characterize and validate *in vitro* assays to assess and characterize tumorgenic potential of cell substrates.** *In vitro* assays will be developed to assess the tumorgenic potential of live cells themselves. *In vitro* assays will also be developed to identify markers of cellular immortalization/transformation. **Part C: Develop, characterize and validate *in vivo* animal models to analyze the oncogenic potential of cellular DNA.** Animal models will be developed to assess the risk of cell substrate DNA itself having oncogenic potential. **Part D: Develop, characterize and validate *in vitro* assays to analyze the oncogenic potential of cellular DNA.** *In vitro* assays will be developed to assess the risk of cell substrate DNA itself having oncogenic potential. **Part E: Develop, characterize and validate assays for detection of novel or latent/occult adventitious agents in cell substrates.** Assays will be developed to screen for infectious agents that are not detected by currently used adventitious agent tests. This will include development of assays to assess the potential for cell substrates to harbor and transmit TSEs. A single offeror may submit proposals for one or more of the five parts, but must submit separate and distinct business and technical proposals for each proposed part.

The NIAID will apply the same evaluation criteria for each Part. Each Part will be scored separately and a competitive range will be determined for each. Awards will be made on the basis of the technical merit of each Part as determined through peer review, the relevance and uniqueness of each Part in relation to Program priorities and balance, and the availability of funds. It is the intent of the Government to make at least one award for each Part. However, the Government reserves the right to make one award, multiple awards, or no award for each Part, which may or may not include all of the proposed Parts, based on overall programmatic need. It is possible that during negotiations an offeror will be asked to delete one or more of the Parts from their proposal if they are considered to not be relevant to the project objectives.

Offerors are informed that NIAID reserves the right to have individual review committee for each Part. If deemed appropriate NIAID may have one committee review multiple Parts.

2. **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) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

3. **TECHNICAL EVALUATION CRITERIA**

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

CRITERIA	**WEIGHT**
1. TECHNICAL APPROACH	**35 POINTS**

A. Proposed Procedures

Offerors will be evaluated on the technical merit, feasibility, and suitability of the proposed procedures in the following areas:

i) The suitability and feasibility the procedure for developing assays.
ii) The suitability and feasibility the procedure for validating assays.
iii) The suitability and feasibility of the procedure for monitoring and evaluating progress performance.
iv) The suitability and feasibility of the proposed time schedule for achieving objectives and milestones.

B. Sample assay validations protocol

Assay validation protocol will be evaluated based on the suitability for generating the body of data needed to validate an assay according to current ICH and FDA guidelines.

C. Use of currently existing technology/animal strains in proposed assay development

D. Suitability and feasibility of the transition plan for allowing the Project Officer access to all data generated under this contract.

2. SCIENTIFIC RATIONALE AND FEASIBILITY **30 POINTS**

A. Soundness of rationale for how the proposed in vitro assay or animal model, if successfully developed and validated, will meet the requirements laid out in this RFP.

B. Convincing rationale of the likelihood of developing the in vitro assay/animal model in the proposed time frame.

C. Critical rationale for the suitability and applicability of the proposed in vitro assay and/or animal model, if validated, for widespread use by manufacturers, regulatory agencies, and/or commercial testing laboratories.

3. PERSONNEL QUALIFICATIONS **25 POINTS**

A. Leadership and Management Staff

Experience and demonstrated success in overseeing assay development and assay validation in accordance with ICH and FDA requirements. Knowledge and understanding of the needs of viral vaccine manufacturers and the FDA in the area of novel cell substrates. In-depth knowledge and experience in working with government agencies, particularly NIH. Proposal must include the documented training, experience, leadership, and availability of a Principal Investigator/Scientist and a Project Manager. Principal Investigator/Scientist and Project Manager may be the same individual.

B. Other Personnel

i) Support Staff. Documented training and experience, and demonstrated competence, in assay development and assay validation. Extensive experience working with cell substrates. If animal model development is proposed, documented training and experience in working with animals and animal model development. Documented training, experience and availability of any proposed subcontractor(s), their documented capability to perform the proposed work, and expertise on similar projects. Adequacy of plans for evaluating the performance of subcontractors.

ii) Staffing Plan. Adequacy and feasibility of staffing plans for the project, including the appropriateness and time commitments of the staff, the mix of expertise, clarity and appropriateness of assigned roles, and evidence that the proposed staff will function as a team. The logistical adequacy of the plan for use of any subcontractor(s) in the conduct of the project, including the time commitments of the professional and technical staff.

4. FACILITIES AND RESOURCES **10 POINTS**

Documented availability and adequacy of facilities, equipment, resources, including shared resources, necessary to carry out all phases of the proposed project in a safe, and secure manner.

TOTAL **100 POINTS**