OMB No. 0990-0115
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: NIH-NIAID-DAIT-04-24	***Just In Time:*** [ ] Yes [X] No	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [ ]No NAICS Code: 541710 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No Total Effort: [ ]
TITLE: **Development of Immune Monitoring Reagents and MHC Typing Technologies for Non-Human Primates**			
Issue Date: **November 20, 2003**	***Due Date: Thursday, March 18, 2004*** ***Time:*** **4:00 PM, EST**		***Technical Proposal Page Limits: 150 (Part I) and 150 (Part II)*** [X] Yes (see "How to Prepare & Submit Electronic Proposals") [ ] No
ISSUED BY: Paul McFarlane Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	[X] NIAID reserves the right to make awards without discussion. ***NO. OF AWARDS:*** [ ] Only 1 Award [X] Multiple Awards		***PERIOD OF PERFORMANCE:*** 5 years beginning on or about 9/30/2004
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 -- Carl Newman --COLLECT CALLS WILL NOT BE ACCEPTED-- Telephone: Direct *Main* 301-496-8371	*Fax* 301-402-0972	*E-Mail* CNewman@niaid.nih.gov	

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

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INTRODUCTION-PART I

This Request for Proposals (RFP) reflects the continuing commitment of the Division of Allergy, Immunology, and Transplantation (DAIT) of the National Institute of Allergy and Infectious Diseases (NIAID) to advancing pre-clinical, non-human primate (NHP) research in the fields of infectious disease vaccine development, transplantation, and autoimmune diseases. Cynomolgus macaque (Macaca fasicularis), Rhesus macaque (Macaca mulatta), Pigtail macaque (Macaca nemestrina), and baboon (Papio hamadrya) are the NHP species that are the primary focus of this RFP, unless otherwise directed by the Government. The RFP details two (2) Parts, each with its own Statement of Work.

PART I – Reagent Development for Monitoring Immunity in Non-Human Primates - solicits proposals to develop, evaluate, produce and distribute new or improved NHP immune monitoring and immune modulating reagents that are needed to: (1) evaluate NHP immune responses in vaccine and adjuvant development for infectious diseases, transplantation research, and autoimmune and infectious diseases models; and (2) develop novel immune-based therapeutics, vaccines and adjuvants. The Government will designate the reagents for development and limited-scale production and distribution based on recommendations by a Scientific Advisory Committee (SAC) appointed by NIAID. The prime Contractor for Part I shall be a domestic organization or institution.

INTRODUCTION-PART II

Part II – Major Histocompatibility Complex (MHC) Typing Technologies for Non-Human Primates - solicits proposals to develop rapid, high-throughput, medium- to high-resolution technologies for major histocompatibility complex (MHC) typing of NHP species. A high degree of MHC gene/allele discovery is required for development and validation of the typing technologies. The prime Contractor(s) for Part II may be a domestic or foreign organization(s)/institution(s).

OFFERORS MAY SUBMIT A PROPOSAL FOR EITHER PART I OR PART II. OFFERORS SUBMITTING PROPOSALS FOR BOTH PART I AND PART II UNDER THIS SOLICITATION MUST PREPARE SEPARATE PROPOSALS FOR EACH PART. PROPOSALS FOR PART I AND PART II WILL BE EVALUATED INDIVIDUALLY AND, POSSIBLY, BY SEPARATE REVIEW GROUPS. IF AN OFFEROR IS FUNDED FOR BOTH PART I AND PART II, THE TWO (2) PARTS WILL BE COMBINED DURING THE CONTRACT NEGOTIATION PHASE.

The central goal of this RFP is to provide the development of products and technologies, with commercialization rights, that will remain freely accessible to the NHP research community. It is anticipated that one (1), five (5) year contract will be awarded for Part I; and one (1) to two (2) contracts will be awarded for Part II, for up to five (5) years duration.

PART I: Reagent Development for Monitoring Immunity in Non-Human Primates

BACKGROUND

Non-human primates (NHP) are the preferred—and sometimes the only-- model for pre-clinical research because they approximate humans in physiology and genetics more closely than any other animal. The most commonly used NHP species in immunology research are: the Cynomolgus macaque *(Macaca fasicularis)*, the Indian and Chinese Rhesus macaques *(Macaca mulatta)*, the Baboon *(Papio hamadryas)*, and the Pigtail macaque *(Macaca nemestrina)*. These species are extremely powerful models to: (1) evaluate the safety and efficacy of candidate vaccines against human pathogens, including bioterrorism NIAID Category A-C agents (See http://www.niaid.nih.gov/biodefense/bandc_priority.htm); (2) develop and evaluate new strategies to prolong the survival of organ and tissue transplants and to induce immune tolerance; and (3) study the pathogenesis of, and evaluate novel immune-based therapies for, infectious and immune-mediated disease. Tremendous immunologic research advances have been made through the use of the NHP model, most notably in AIDS pathogenesis, treatment, and vaccine development.

Various immune monitoring and modulating reagents developed for human research and clinical use cross-react to varying degrees with assorted NHP species. However, many reagents and therapeutics for human studies either do not cross-react with NHP species or are not available for use in NHP research, as is the case for many immune-based therapeutics after clinical trials are underway. An additional impediment is the decreasing availability of the Indian Rhesus macaque, which has been the mainstay of NHP research. Because of this Indian Rhesus shortage, many researchers are beginning studies with other monkey species. A variety of reagents that react with the Rhesus do not cross-react with other species, or cross-react only sub-optimally.

Key immunologic reagents for the NHP model are needed for researchers to effectively: (1) monitor the dynamics and parameters of the NHP immune responses *in vitro* and *in vivo*; (2) define immune response mechanisms through the *in vivo* depletion of specific immune cells; (3) develop novel immune-based adjuvants for vaccines; and (4) develop innovative therapies to induce immune tolerance to transplanted tissues and organs. The development of critical immune monitoring and modulating reagents for the NHP is essential for the rapid and effective development of vaccines for pathogens that are potential bioterrorist threats. These research tools will also greatly enhance the utility of this key research model; and will accelerate research targeted at developing cures and treatments for immune mediated diseases, as well as emerging and reemerging infectious diseases.

PART II: MHC TYPING TECHNOLOGIES FOR NON-HUMAN PRIMATES

BACKGROUND

As in the human genome, the major histocompatibility complex (MHC) is the most polymorphic region of NHP genomes. Genes of the MHC complex encode surface proteins that regulate immune responses to pathogens, tumors, and transplanted organs by presenting peptides, derived from these foreign materials, to $CD4^+$ and $CD8^+$ T cells. Identification of the MHC alleles, both MHC Class I and II, and the MHC-binding peptides can accelerate critical vaccine development strategies for potential agents of bioterror, and also allow selective breeding of NHP colonies to facilitate this research. Indeed, the conservation of MHC peptide-binding motifs between humans and Rhesus macaques suggests that vaccine candidates, identified in NHPs, may be effective in humans. In organ and tissue transplantation, if a donor and recipient do not possess identical MHC genes, the MHC molecules of the donor organ or cells may provoke a vigorous immune response by the recipient's T cells, resulting in graft rejection. Similarly, in hematopoietic stem cell transplantation, T cells in the graft may respond to recipient tissues, resulting in graft-versus-host disease (GVHD). Knowledge of the specific MHC genes expressed in the donor and recipient would greatly accelerate studies into new strategies to prevent graft rejection and GVHD.

Based primarily on Indian Rhesus macaque MHC sequence information, NHPs, like humans, appear to have a high degree of MHC polymorphism. Interestingly, the number of MHC gene alleles present in an individual NHP genome exceeds that of humans due to gene duplication and unusually high levels of recombination; however, the degree of polymorphism between individual MHC alleles may be less in NHPs compared to that of humans. Because of the overall high degree of polymorphism and the relative lack of information of MHC gene sequences in NHP species, identification of alleles present in individual animals requires time- and labor-intensive techniques. To accelerate immunological studies in NHP species, improved high throughput technologies for MHC allele and/or haplotype identification are required.

Traditional, serological methods for MHC typing are very limited for NHPs, due in part to the scarcity of specific antibodies. In addition, antibodies, which recognize conformational structures on the MHC protein, often cannot discriminate among alleles. Therefore, DNA-based methods are required. Currently, most DNA-based methods rely on DNA sequence-specific primer amplification or hybridization, conformational analysis, and/or gene sequencing to identify MHC alleles. Current high-resolution methods, direct sequencing and reference strand-mediated conformational analysis, are highly accurate, but extremely labor-intensive and difficult to employ in a large number of laboratories. Furthermore, all these DNA-based methods are limited by the lack of knowledge of the numbers and sequence variation of alleles for each MHC locus. While far more is known about the number and sequence differences in Indian Rhesus macaque MHC Class I alleles, typing methods are still not widely available, are time consuming and require a high level of expertise. Moreover, typing for MHC Class II alleles, which is very important for all pre-clinical immunology research, is far behind that for MHC Class I molecules and, therefore, requires a parallel effort.

Robust, high-throughput MHC typing in all NHP species will require better DNA-based technologies and more extensive knowledge of the loci and allelic differences for all the MHC Class I and II molecules. To have the greatest utility for end users, DNA-based technologies

must be: relatively high-throughput, easy to manipulate, readily available, affordable, and easily upgraded as new allelic information becomes available.

PART I: Reagent Development for Monitoring Immunity in Non-Human Primates

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all 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 and as approved and specified by the NIAID Project Officer. The NIAID will appoint a Scientific Advisory Committee to provide recommendations regarding reagent and NHP species priorities to the NIAID Project Officer. Responsibility for the development, production, and delivery of all products under this contract rests with the Principal Investigator. **See Notes 1-4 to the Offeror.**

Specifically, the Contractor shall:

A. **Reagent Development**

1) **Identify reagents that include monoclonal/polyclonal antibodies (mAb or pAb, respectively), receptors/ligands, chemokines/cytokines, chimeric/recombinant proteins/mAbs, and other novel state-of-the-art reagents for application to:**
   (a) *in vitro*, *in vivo* and *ex vivo* detection or imaging of NHP cell surface or soluble molecules to monitor immune responses including, but not limited to, flow cytometric, histologic, quantitative PCR, ELISpot, and ELISA methodologies;
   (b) *in vivo* immune modulation or immune-based therapy; and
   (c) *in vivo* depletion of specific immune cells or subsets of cells in NHP models of transplantation, vaccine/adjuvant development and evaluation, and immune-mediated and infectious diseases.

2) **Submit a prioritized list of candidate reagents with a detailed justification of need and special considerations for development of each candidate reagent to the NIAID Project Officer for review by the NIAID Scientific Advisory Committee (SAC)**. For proposed antibodies, discuss and justify whether (1) the immunizing protein or DNA should be of non-human primate origin, rather than human origin; and (2) the resulting monoclonal antibody, if proposed for *in vivo* use, should be a human/mouse chimeric antibody or a fraction thereof. Provide similar species-specific justifications, only where applicable and reasonable, for the development of soluble molecules, such as cytokines, chemokines, or other ligands or soluble receptors designed for *in vivo* use. The identification process may include the purchase or acquisition of commercial and/or non-commercial source antibodies or proteins for the evaluation of reactivity or suitability. The Contractor shall submit a plan for the continued identification process and shall provide to the Project Officer in every quarterly and annual report the reagents identified by this process.

   The Government may or may not elect to proceed with development of the particular reagents proposed by the Contractor based on the advice of the SAC and/or needs of the Government. The Project Officer may direct the Contractor to develop reagents identified and recommended by the SAC, based on the needs of the Government. The Contractor shall proceed to the tasks specified in Statement of Work Part I. A. 3) below only after Project Officer approval of the reagents to be developed. **See Note 5 .**

3) **Provide a detailed development proposal within 30 calendar days following receipt of a request for specific reagent(s) from the NIAID Project Officer, or within 15 calendar days of receipt of a request to modify a specific reagent.** The detailed proposal shall contain performance milestones and dates to accomplish each element of the work, together with a detailed budget. NIAID, with members of the SAC as determined by the Project Officer, will conduct an expedited review of the reagent development proposal and proposed budget. Upon approval, the contractor shall carry out the developmental tasks, adhering to the milestone dates and proposed procedures.

4) **Develop and/or modify mAb/pAbs, receptors/ligands, chemokines or cytokines, chimeric/recombinant proteins/mAbs, or novel, state-of-the-art reagents**. Developmental techniques may include items 3a-3h below, but are not limited to these methods. The Contractor shall propose and implement particular methods in consultation with and upon approval by the Project Officer. **See Notes 6 and 7.**
    a. Recombinant methodologies to create chimeric mAbs or fragments thereof. **See Note 5.**
    b. Development or optimization of suitable expression vectors and/or modification of flanking or coding DNA sequences within vectors to optimize protein expression.
    c. Cloning and sequencing of the non-human primate gene(s).
    d. Immunization, cell line development, isolation and production of clones (hybridomas) of desirable immunoglobulin (Ig) subclasses or optimal cross-reactivity among non-human primate species.
    e. Creation and/or screening of Ab libraries with non-human primate proteins.
    f. Adduct technologies for tagging proteins/antibodies for *in vitro* and *in vivo* uses, e.g., green fluorescent protein, fluorophore, and biotin modification.
    g. Multimer and Ig fusion protein development.
    h. Production of fully human or fully non-human primate Abs through the use or development of transgenic mice or the screening of fully human or NHP Ab libraries.

5) **Validate, at a minimum, the recognition specificity, activity, unique characteristics, potency and purity, before production scale-up,** of the newly defined mAb, pAb, ligands, or chimeric/recombinant proteins. The Contractor shall assess reactivity across multiple NHP species. Validation may require development of new assays and reagents, as determined by the Contractor in consultation with the Project Officer. Validation may be prioritized by the Contractor, in consultation with the Project Officer, to the most promising reagents, particularly those with cross-species reactivity. Appropriate methods for validation may include, but are not limited to, one or more of the following:
    a. immunoprecipitation and gel electrophoresis
    b.western blotting
    c. in vitro testing with non-human primate cells, fluid or tissues **(See Note 8b.)**
    d. flow cytometry
    e. ELISA assays
    f. immunoglobulin isotyping
    g. DNA or protein sequence confirmation of recombinant products
    h. biological activity, including receptor blockade/modulation

i. in vivo testing, in consultation with and approval by the Project Officer **(See Note 5, 7 and 8a.)**

6) **Develop and optimize *in vitro* assays and protocols for use of all reagents and assays,** including controls, standards, and/or antibody pairs as necessary. The Contractor shall evaluate and optimize the potency, specificity, and reproducibility of the assays developed. The assays may include, but are not limited to, those listed in Part I A.1a of the Statement of Work.

7) **Prepare and distribute aliquots of materials and protocols for use,** in conjunction with Part I. A. 5 of the Statement of Work, to interested members of the NHP research community for evaluation, in consultation with and as approved by the Project Officer.

8) **Maintain detailed development, production, and validation records for assays, protocols and reagents developed under the Contract.** At a minimum, these records shall include: the laboratory notebooks; stock numbers and sources of materials; method; protocols; immune assay readouts; standards; and storage location of reference samples and materials produced.

B. **Production, Quality Control, and Inventory**

1) **Provide small-scale process development for optimized production, purification, sterilization, and storage of developed reagents.** Maintain a development report of batch production.

2) **Produce small-scale batches of reagents developed, in addition to the initial developmental batch(es),** after discussions with and upon approval by the NIAID Project Officer. Provide established clones to the American Type Culture Collection (ATCC) or other repository, designated by the Project Officer, and/or provide aliquots of cell lines/clones to investigators or to another facility for production and distribution, in consultation with and approval by the Project Officer. The Contractor shall provide capability for the production and purification of at least 3 specificities at any given time, at an estimated rate of 500 mg each of purified protein per four (4) months. However, it is acknowledged that production levels may vary significantly between specificities and individual clones and that smaller quantities may be adequate for some uses. GMP grade material is not required; however, low endotoxin levels will be required for in vivo use and all products shall be provided sterile.
See Notes 7 and 10.

3) **Purify products**. Provide documentation that lyophilization will be available, if and when appropriate or as required by the Project Officer.

4) **Establish quality control and assurance procedures for each product line and implement these procedures for each batch,** including, but not limited to, characterization as to purity, concentration, specificity, biological activity, potency, endotoxin level and sterility, and other parameters as may be specified by the Project Officer with the advice of the SAC and/or by emerging technologies.

5) Provide and implement plans to evaluate, standardize, and optimize reagents for *in vivo* use, in consultation with and as approved by the Project Officer. [See Part A.1 b and c of the Statement of Work].
See Notes 7 and 8a.

6) **Provide and implement plans to**: (1) receive and store cell lines or vectors; (2) prepare and label aliquots of cell lines, vectors, and developed reagents for limited distribution; (3) provide controlled storage; (4) maintain inventory; and (5) ship reagents and reagent antibody pairs for limited distribution. Ensure reliability of storage systems and backup support systems for storage. Maintain electronic inventory and distribution records.

C. **Distribution and Administration**

Specifically the Contractor shall:

1) **Develop and implement an electronic data management plan.** Compile and maintain an up-to-date, secure computerized database of all administrative information concerning the project, including development details, reagents available, reagents under development, assay results, production protocols, batch records, reagent requests, distributions, and inventories. Detailed electronic procedure manuals with all protocols and updates shall be submitted to the Project Officer on a routine basis. The database shall use commercially available computer software.
See Note 9.

2) **Provide and implement a plan to** (1) receive electronic requests for the limited-distribution of reagents or cell lines and (2) establish request requirements and assurances, including compliance with animal protection regulations, provide information for intended use, brief description of project(s) and an agreement to acknowledge the Resource in publications. Transmit requests to the Project Officer for NIAID approval within 7 days of receipt. The Contractor shall also respond within 7 calendar days after NIAID approval of a request to requestor queries regarding the status of orders. Requesting investigators will pre-pay for express parcel delivery costs, except when evaluation is specifically requested of interested investigators. The Contractor shall provide cost of shipping containers, wet or dry ice if required, and handling. The Contractor shall provide a package insert detailing complete protocols, reagent specifications, and guidelines for reagent use to all requestors.

3) **Provide and implement a plan to maintain effective communication,** including electronic communication with all subcontractors, the Project Officer, and members of the SAC. Provide for frequent updates, discussion of problems/progress/solutions as needed via conference calls or electronic communications with relevant subcontractors, the Project Officer and members of the NIAID SAC.

4) **Provide an electronic monthly status report within 5 working days of the end of each month to the Project Officer** on the status all reagents and assays under production, rather than those under development; as well as reagent requests received, delivered, pending approval, or pending shipment with anticipated dates of delivery.

5) **Maintain communication with investigators in the NHP field about their reagent needs and their results of reagent evaluations.**

6) **Provide scientific and technical personnel with the training and experience necessary** to meet all requirements of the Statement of Work. Provide travel and related expenses to appropriate personnel to attend one domestic scientific meeting per year. **See Note 8.**

7) **At a minimum, participate in an annual two-day meeting**, which may include, based on discussions with the Project Officer, the Principal Investigator, one (1) representative from each subcontract, and members of the NIAID SAC, to be held in Bethesda, Maryland. The Principal Investigator shall also participate in an additional, annual one-day meeting with the Project Officer and members of the SAC, as determined by the Project Officer. **See Note 8d.**

8) **Administer the Contractor's patent rights in a manner that will not conflict with the central goal of this contract**, which is to make all reagents and protocols freely accessible, albeit not necessarily without cost, to the non-human primate research community. **See Note 10.**

9) **Within three (3) months of award, provide and implement a plan, including milestones, to create and maintain an updated public website,** in consultation with the Project Officer, that shall at a minimum provide information on the facility; reagents available, but does not need to reflect real-time inventories; procedure to request a reagent/cell line or link to where the reagent or cell line may be obtained; technical specifications, protocols, and updated considerations for reagent/assay use or a link to this information; updated cross-reactive antibodies identified by the resource that are commercially or non-commercially available (alternative arrangements may be directed by the Project Officer to contribute to and/or link to existing publicly accessible websites for this information). It is not the intent of the Government to duplicate public databases. Website contents shall require the approval of the NIAID Office of Communications and the Project Officer. In addition, the Contractor shall provide and implement a plan to inform the scientific community of the existence of the resource and website.

10) **Six months prior to the contract completion date, or as requested by the Project Officer, the Contractor shall provide a plan for the orderly transition and transfer of all data, databases, protocols, procedure manuals, and reagent/product inventory generated during the life of the contract** to a subsequent contractor or other party designated by the Project Officer. The plan shall provide for a minimum interruption of full operations until expiration of the contract. The Contractor shall work with the Project Officer and Contracting Officer to refine and complete the plan. The final transition plan shall be delivered no later than three (3) months before the contract's expiration date.

End of Statement of Work Part I

PART II: MHC TYPING TECHNOLOGIES FOR NON-HUMAN PRIMATES

STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all 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.

Specifically, the Contractor shall:

A. **Develop high-throughput molecular tools, methods, and technologies for the robust identification/typing of MHC Class I and Class II gene loci and alleles** in one or more of the following NHP species: Cynomolgus macaque (*Macaca fasicularis*), Indian and Chinese Rhesus macaques (*Macaca mulatta*), baboon (*Papio hamadryas*), and Pigtail macaque (*Macaca nemestrina*); MHC designations, Mafa, Mamu, Paha, and Mane, respectively. If the development/focus will be limited to one species, it shall be the Cynomolgus macaque. Based on the needs of the Government and as specified by the NIAID Project Officer, the Contractor shall include MHC typing of the NIAID Cynomolgus breeding colony over the course of the contract, with methodologies developed, and typing of the NIAID Rhesus breeding colony, if technology is developed for the Indian Rhesus.

   The Government may direct the Contractor to develop technologies for additional or alternative species according to the progress of the science, achievement of milestones, and the needs of the Government.

   See Notes 11 and 12.

B. **Provide and implement a plan to develop high-throughput, high-resolution (if required) MHC typing, and haplotype determination** that is required or optimal for some areas of transplantation research, e.g., bone marrow or stem cell transplantation. Additional methodologies developed and validated may include intermediate-level resolution typing. Methodologies may be adaptations or modifications of current methods to create more cost-effective, high-throughput assays with an emphasis on accuracy, reproducibility, ease-of-use and ability to translate to the scientific community.
   See Note 13.

C. **Provide and implement a detailed plan to develop/design and/or optimize primers/probes for the methodology under development,** using known sequences in addition to gene discovery/cloning/sequence efforts required to accomplish the goals set forth in this Statement of Work and as part of this Contract.
   See Note 14.

D. **Validate all methodologies developed** in Part II, A. and B. above, including comparison to exiting high-resolution technologies.

E. **Identify, develop and validate controls and standards for technologies developed**, such as MHC-typed Epstein Barr Virus transformed B cell lines (BLCL), cell lines transfected/transduced with defined MHC alleles, DNA stocks of cell lines, and/or DNA from

cloned alleles. Develop and provide internal controls and standards with typing methodology and procedures for use.

F. **Develop or adapt commercially available analysis software** for the technology using standard software good engineering practices, if required.

G. **Develop and maintain a database, using commercially available relational database software management,** to track typing data, validation/comparison of methods data, and sequence and primer information collected during the life of the contract. Provide updated information/electronic data on a quarterly basis as directed by the Project Officer.

H. **Submit all sequence information to** applicable public databases, e.g. GenBank, within a timeframe determined in consultation with the Project Officer or as specified by the Project Officer. The minimum amount of information for submission shall be equivalent to that required by GenBank (See http://www.ncbi.nih.gov/Genbank/GenbankOverview.html).

I. **Develop and implement a plan to establish and maintain a website with primer information,** typing results, controls generated, researcher feedback, contact procedure, available resources, protocols and methodologies developed and links to other appropriate public websites or databases. Creation of this public website shall be in consultation with, and as specified by, the Project Officer. It is not the intent of the Government to duplicate public databases. It is entirely possible that the Contractor for Part II will be required to contribute to the Website created for Part I, rather than generate a new website. Website contents shall require the approval of the NIAID Office of Communications and the Project Officer. In addition, the Contractor shall provide and implement a plan to inform the scientific community of the existence of the resource and website. **See Note 14.**

J. **Establish and maintain close ties** with the NHP research community. The Principal Investigator and one member each from any subcontracts, at the discretion of the Project Officer, shall attend one (1), two (2) day NIAID Scientific Advisory Committee meeting per year in Bethesda, Maryland.
See Note 14 and Note 2 in Part I of the Statement of Work for details about the NIAID-appointed SAC.

K. **Develop and implement a plan to provide training to interested researchers**, with the approval of and/or at the request of the Project Officer in the technology/technologies developed. **See Note 14.**

L. **Administer the Contractor's patent rights in a manner that will not conflict with the central goal of this contract**, i.e., to make all reagents, technology, software, and protocols freely accessible, albeit not necessarily without cost, to the NHP research community.
See Note 15.

M. **Develop and implement a plan to distribute**, on a limited basis during the life of the contract and in consultation with and/or at the request of the Project Officer, primers and/or sequence of primers, protocols, controls and specialized software and non-commercialized technology generated.

See Note 14f.

N. **Six months prior to the contract completion date (or as directed by the Contracting Officer), the Contractor shall provide a plan for the orderly transition and transfer of all data, databases, protocols, procedure manuals, and complete reagent/product/cell line inventory generated during the life of the contract to a subsequent contractor or other party designated by the Contracting Officer.** The plan shall provide for a minimum interruption of full operations until expiration of the contract. The Contractor shall work with the Project Officer and Contracting Officer to refine and complete the plan. The final transition plan shall be delivered no later than three (3) months before the contract's expiration date.

End of Statement of Work Part II

Notes To Offerors: Part I

Note 1: The NHP species that are the primary focus of this RFP are: the Cynomolgus macaque (*Macaca fasicularis*), Rhesus macaque (*Macaca mulatta*), Pigtail macaque (*Macaca nemestrina*), and baboon (*Papio hamadrya*). Reagent development for additional species of non-human primates may be required as recommended by the NIAID appointed Scientific Advisory Committee (SAC) or the needs of the Government. **See Note 2 to Offeror.**

Note 2: NIAID will appoint a SAC within one (1) month of the Contract award. The SAC will meet, either in Bethesda or by teleconference within 45 days of the contract award to make initial recommendations and prioritizations. The SAC will consist of investigators with a broad range of expertise in NHP research and will, at a minimum, (1) provide and prioritize recommendations for reagents and assays to develop; (2) evaluate recommended reagents or assays for development put forward by the Contract Principal Investigator; (3) provide advice to NIAID and the Contractor on issues dealing with reagent development, production, and distribution; and (4) evaluate the Contractor's reagent development proposals or modification thereof, when specified by the Project Officer.

Note 3: **Subcontracts:** The Government is aware that no single organization or institution may have the expertise and facilities required to perform all requirements set forth in this Statement of Work. Subcontracting agreements are acceptable and are encouraged in order to accomplish the work outlined in this solicitation. Subcontracting to foreign sites is acceptable. The primary Contractor for Part I shall be a domestic organization or institution. The relationship between the subcontractor(s) and the prime Contractor in conducting the tasks specified in the Statement of Work should be clearly delineated in the Technical Proposal. In addition, the Technical Proposal must describe in detail a management plan defining how the Contractor will manage and coordinate the work of the subcontractor(s).

Note 4: In the Technical Proposal, Offerors must address all components of the Statement of Work and, where applicable, fully describe proposed methods, advantages and disadvantages of the proposed methods, potential problems and solutions, alternative approaches, and the relevant experience to performing the tasks set forth in each item of the Statement of Work. Offerors must provide in the technical proposal appropriate documentation of previous and current projects of a similar nature, including the contract number or grant number, if applicable, the sponsoring agency, and a description of the project. The Technical Proposal, including biographical sketches, shall not exceed 150 total pages.

Note 5:The Technical Proposal must include a prioritized list of candidate molecules with a detailed justification of need and special considerations for development of each candidate molecule, addressing all components of Part I A.1 and 2 of the Statement of Work. The prioritized list of candidate reagents, with detailed justifications, must include a minimum of ten (10) unique specificities with a minimum of two (2) specific examples for any one of categories Part I. A.1a-1c of the Statement of Work. For Part I. A. 1a of the Statement of Work, include a minimum of one specificity needed for ELISpot or ELISA assays. Reagents proposed for development by the Offeror may or may not be selected or recommended by the SAC and the Project Officer for development by the Contractor.

Note 6: In the Technical Proposal, the Offerors must provide a detailed plan, which initially may be the verified access to expertise and appropriate reagents and tools, to perform each developmental method example presented in Part I. A.4a-4g of the Statement of Work. No detailed plans are required for Part I A. 4h of the Statement of Work. However, Offerors must discuss the need or potential benefits, if any, of Part I.A.4h of the Statement of Work.

Note 7: In the Technical Proposal, Offerors must provide detailed plans for the development of three (3) proposed reagents (from the Offeror's priority list requested under Note 5 in Categories 1-3 below) for which there is not a commercial or non-commercial source available for research use, or for which the currently available products are of less than optimal activity or specificity. Offerors must propose at least one of the three reagents to be developed from the NHP gene cloning stage. Provide details of all methods proposed. Proposals for each reagent shall include all relevant steps for the development, evaluation/validation, optimization for production, production and purification of approximately 10 mg of Category 1 and 500 mg of Categories 2-3, below.

The Government may or may not elect to proceed with development of the particular reagents proposed by the Offeror. Address and fully describe all methods and all applicable components of the tasks set forth in Part I of the Statement of Work in the development and limited-scale production and purification of the proposed reagents.

> Category 1: One high-priority monoclonal antibody or antibody pairs for protein detection by either ELISpot or ELISA;
> Category 2: One high-priority recombinant/multimeric protein for *in vivo* immune modulation or therapy, and;
> Category 3: One high-priority monoclonal antibody for *in vivo* immune cell/subset depletion.

Discuss strategies for conducting *in vivo* evaluation that will require the least number of monkeys. Discuss under what circumstances the same monkeys could be used to evaluate multiple products. The Offeror shall not name or contact investigators for support of *in vivo* or *in vitro* evaluation unless the investigator(s) will be a proposed subcontractor or collaborator in the development of the reagent(s).

Note 8: For purposes of the Business Proposal, prepare a one-year budget and cost estimates for Part I Statement of Work in which the following apply:
At the present time, the Government does not have exact numbers of products to develop nor the specific quantity and related costs of production. The Offerors should assume that the three (3) requests in Note 7, Categories 1-3 will be developed and produced on a small scale, in the first year, and that approximately 10 mg of Category 1 and 500 mg of Categories 2 and 3 quantities will be required. For purposes of Technical and Business Proposal preparation, assume that the Government will provide other arrangements for the production and distribution of larger quantities.

a) It is possible that limited in vivo testing will be conducted by interested investigators that may limit the costs to the Contractor. However, for the purpose of Business Proposal preparation, assume for in vivo testing and validation that up to eight (8) monkeys of a single species will be supplied to the Contractor for shipping/handling costs alone. All other costs

related to proposed in vivo testing should be included in the Business Proposal. Assume that the same monkeys may be used for in vivo validations proposed in the Technical Proposal (**See Note 6, Reagent Categories 2 and 3**).

b) For in vitro testing, assume that non-human primate blood samples will be provided for the cost of shipping and handling. The NIAID/DAIT has breeding colonies of Indian Rhesus and Cynomolgus macaques. If another species is proposed, make the same assumptions for cost estimating purposes.

c) Assume that fifty (50) requests for shipment of products under development or fully developed will be handled in the first year of the contract and that requestors will pay only the shipping costs. In addition, include the costs of twenty (20) shipments, requiring dry ice, at the Contractor's expense for pre-production evaluation by interested investigators.

d) Cost estimates for the annual, two-day SAC meeting shall include travel costs (transportation, meal, hotels, etc) for the Principal Investigator, additional staff of the contractor, and two subcontractor staff members. Cost estimates for the additional one-day meeting shall be only for the Principal Investigator. For cost estimate purposes, assume that travel and registration expenses will be paid for three (3) personnel, including the Principal Investigator, to attend one scientific meeting a year.

e) The Government estimates that performance of the activities presented in SOW Part I will require 525 % effort or 9,940 hours per year. This estimate includes the Principal Investigator, research scientists, technicians, administrative staff, and website maintenance and development staff. This estimate is for the Offerors' information only and is not to be considered restrictive for proposal purposes.

Note 9: The Technical Proposal must include detailed proposals of electronic data management plans, the plan to receive and process electronic requests, and the plans to maintain communication with investigators in the NHP field about their reagent needs.

Note 10: Individual and institutional intellectual property rights and rights to inventorship under U.S. patent law will not be affected by participation in this RFP. The involvement of the NIH in the performance of this contract will not affect ownership rights of the participating parties beyond U.S. Government rights under any funding agreement as specific under 35 U.S.C. #202. All licensing agreements entered into by the Contractor for completion of any and all tasks listed in the SOW shall be transferable to the Government. Contractors are strongly encouraged to protect new technologies in a timely manner and to ensure their availability to the research community.

Notes To Offerors

Part II: MHC Technology Development

Note 11: MHC typing technologies for the Cynomolgus and the Indian Rhesus macaques are currently the highest priority species for NIAID and, most particularly, the Cynomolgus macaque. Technical proposals must include proposed plans to develop MHC Class I and Class II typing methodology for, at a minimum, the Cynomolgus macaque. However, the primary focus of a Technical Proposal may be another of the species listed in Statement of Work Part II. A. Considerably more is known about the MHC gene sequence of the Indian Rhesus macaque and, therefore, the use of Rhesus as the primary proof of principal species in the early technology development stage is appropriate, if preferred by the Offeror.

NIAID/DAIT owns out-bred breeding colonies of both Indian Rhesus and Cynomolgus macaques that will be available as a source of blood for the extraction of DNA. For cost estimating purposes, assume that 100 Cynomolgus macaques from the NIAID breeding colony will be typed, and include shipping costs for 10 shipments of blood for DNA extraction in the Business Proposal. If Indian Rhesus macaque technology is developed, assume that 200 Rhesus macaques will be typed, and include shipping costs for 20 shipments. The Government's priorities may change during the course of this Contract and, therefore, the Contractor's efforts may be expanded or redirected to additional or other species. On an annual basis, at a minimum, the NIAID will enlist advice, recommendations and evaluation of this program from the NIAID Scientific Advisory Committee (SAC) established for Part I of this RFP.

For the purposes of this RFP the definition of high-resolution typing is direct sequencing methods and reference strand conformational analysis (RSCA). Whereas, the definition of medium or intermediate resolution typing includes methods, such as, but not limited to, polymerase chain reaction-sequence specific primer (PCR-SSP) and sequence specific oligonucleotide probe (SSOP) typing. (**See Notes 1 and 2 to Offeror, Part I.**)

Note 12 **Subcontracts:** The Government is aware that no single organization or institution may have the expertise and facilities required to perform all requirements set forth in this Statement of Work. Subcontracting agreements are acceptable and are encouraged in order to accomplish the work outlined in this solicitation. Subcontracting to foreign sites is acceptable. The Prime Contractor may be a domestic or foreign institution or organization. The relationship between the Prime Contractor and proposed subcontractor(s) in conducting the tasks specified in the Statement of Work must be clearly delineated in the Technical Proposal. In addition, the Technical Proposal must describe in detail a management plan defining how the Contractor will manage and coordinate the work of the subcontractor(s). If the Offeror or a proposed subcontractor is a commercial firm, the Technical Proposal must address how potential conflicts of interest or intellectual property rights issues will be resolved.

Note 13: The Technical Proposal must address all components of the Statement of Work for Part II, including a detailed description of proposed methods, the advantages and disadvantages of proposed methods, potential problems and solutions, alternative approaches, and the relevant experience to perform the tasks set forth in each item of the Statement of

Work. The total number of pages for the Part II Technical Proposal, including biographical sketches, shall not exceed 150 pages. Provide appropriate documentation of previous and current projects of a similar nature, including the contract number or grant number, if applicable, the sponsoring agency, and a description of the project. The Technical Proposal must also include a discussion of the state-of-the-science for MHC typing in NHP, as well as a discussion of the various specific MHC typing needs of the diverse NHP research community, including the special needs to optimally conduct research for solid organ, tissue and bone marrow/stem cell transplantation, and in which situations intermediate-resolution technology would not be adequate.

Note 14: The Business Proposal for Part II must include a budget for all requested years of the contract [up to five (5) years] with the following considerations:

a) Although a full proposed plan for a website is required in the Technical Proposal, for purposes of the Business Proposal, Offerors should assume that the Contractor will contribute to the website developed under Part I. Labor costs required to populate this database and coordinate with the Contractor for Part I should be included in the Offeror's business proposal.
b) Although training of investigators would likely not take place in the first year of the Contract, assume only for the Business Proposal preparation that five (5) investigators will be trained per year and would be expected to cover all their own travel costs.
c) The Government estimates that for performance of the activities presented in the Statement of Work for Part II, it may require as much as 635% total effort or 13,208 total hours per year for a large scale technology development effort. This estimate includes the Principal Investigator, research scientists, technicians and administrative staff. This estimate is for the Offerors' information only and is not to be considered restrictive for proposal purposes.
d) Travel and related registration costs should be included for the Principal Investigator and one other scientific personnel to attend one scientific meeting a year. In addition, costs should be included for the Principal Investigator and one person from any subcontract to attend one (1), two (2) day meeting per year in Bethesda, Maryland with the Project Officer and SAC.
e) Include the cost of NHP blood sampling and shipments and assume that there will be six (6) shipments of twenty (20) frozen blood samples per year for validation.
f) Calculate the costs of supplying technology/primers on a limited basis to the research community in the Business Proposal. Specific details associated with the costs are open for negotiation if necessary.

Note 15: Individual and institutional intellectual property rights and rights to inventorship under U.S. patent law will not be affected by participation in this RFP. The involvement of the NIH in the performance of this contract will not affect ownership rights of the participating parties beyond U.S. Government rights under any funding agreement as specific under 35 U.S.C. #202. All licensing agreements entered into by the Contractor for completion of any and all tasks listed in the SOW shall be transferable to the Government. Contractors are strongly encouraged to protect new technologies in a timely manner and to ensure their availability to the research community. Administration of the Contractor's intellectual property rights arising from work performed under this contract shall be in a manner that will not conflict with the goals of this

RFP, which is to make all generated materials, techniques, protocols, and data widely accessible to the research community in a timely manner.

REPORTING REQUIREMENTS AND DELIVERABLES
Part I

Development of Immune Monitoring Reagents

As part of the work to be performed under this contract, the Contractor shall prepare and deliver the following reports throughout the period of performance. The exact submission schedule will be negotiated and established in the contract document.

I. Quarterly Progress Reports

The Contractor shall submit electronic reports via email to the Project Officer and the Contracting Officer and two (2) hard copies on the 15th of the month, following the end of each quarterly performance period. The original shall be submitted to the Contracting Officer, with a copy to the Project Officer. Each quarterly report shall include the following:

(A) A cover page that lists the contract number and title, performance period covered, author(s), Contractor's name and address, telephone number, fax number, e-mail address, and submission date.

(B) An executive summary, to include, but not necessarily limited to:

1) A brief overview of the status of the project, including personnel, requests processed, feedback received, research and development activity.
2) A brief overview of the work that was completed for the reporting period and/or justification for failure to complete intended work, fulfillment of production goals, or performance of unintended work..
3) A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period.

(C)A full description of:

1) Status of work in progress for development and production of reagents, including a summary list organized by type of reagent.
2) The work performed during the reporting period.
3) A full disclosure of the results obtained during the performance period, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented.
4) Inquiries for new development of reagents from the community.
5) Requests for reagents not available and any new reagents, with justification, identified and recommended for development/production.
6) Website updates.
7) Shipment records summarized in table form for reagents, including:
    a) Identification of the item shipped
    b) Quantity of item shipped
    c) Date of shipment
    d) Name and address of recipient
    e) Quality feedback or follow-up.

8) Copies of manuscripts (published or unpublished) derived from research performed under the contract and copies of all abstracts, manuscripts, preprints and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period.

9) An anticipated work plan for the next quarter.

10) Any additional information requested within the Statement of Work, or as requested by the Project Officer.

II. Annual Reports

The fourth Quarterly Report shall represent the Annual Report and follow the format and time schedule of the Quarterly Report. The Annual Report shall summarize progress for the entire Contract year and be submitted as with the Quarterly Report on the 15th of the month following the end of the reporting period.

III. Final Report

The Contractor shall submit copies (as specified for the Quarterly Report above) of the Final Report that document and summarize the results of the entire contract period of performance. This report will be submitted no later than the completion date of the Contract. The report shall include the following:

(A) A cover page that lists the contract number and title, performance period covered, author(s), Contractor's name and address, telephone number, fax number, e-mail address, and submission date.
(B) An introduction describing the purpose and scope of the effort, including a summary of salient results, not to exceed 200 words.
(C) An executive summary, to include an overview of the fulfillment of production goals and the specific aims set forth in the Contract.
(D) A detailed description of all the work performed, the results obtained, and a discussion of the relevance of the results and impact on the NHP research community.

IV. Other Deliverables

Any additional items, deliverables or reports required in the Statement of Work at intervals requested, including but not limited to: one electronic and hard copy of reagent request for development proposals and any modifications (Statement of Work Part I A.3.) provided to the Project Officer and hard copy original to the Contracting Officer; electronic procedure manuals for reagents developed to the Project Officer (Statement of Work, Part I C. 1.). In addition, delivery at least one (1) month prior to the contract completion date any equipment supplied or procured under this contract, the complete database and source codes of reagent requests and all genetic, biochemical, and biological materials acquired, developed, or inventoried during the contract period.

Part II
MHC Typing Technologies for Non-Human Primates

As part of the work to be performed under this contract, the Contractor shall prepare and deliver the following reports and data throughout the period of performance. The exact submission schedule will be negotiated and established in the contract document.

I. Quarterly Progress Reports

The Contractor shall submit an electronic report to the Project Officer and two (2) hard copies on the 15th of the month following the end of each quarterly performance period. The original shall be submitted to the Contracting Officer, with a copy to the Project Officer. Each quarterly report shall include the following:

(A) A cover page that lists the contract number and title, performance period covered, author(s), Contractor's name and address, telephone number, fax number, e-mail address, and submission date.

(B) An executive summary, to include, but not necessarily limited to:

1) An overview of the status of the project, including personnel, requests processed, research and development activity;
2) A brief overview of the work that was completed for the reporting period and/or justification for failure to complete intended work, fulfillment of production goals, or performance of unintended work.
3) A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period.

(C) A full description of:

1) Status of work in progress for development and production of primers, controls, standards, technology, sequencing status, data submission and website update.

2) The work performed during the reporting period.

3) A full disclosure of the results obtained during the performance period, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented.

4) Shipment records, if applicable:
   a. Identification of the item shipped
   b. Quantity of item shipped
   c. Date of shipment
   d. Name and address of recipient
   e. Quality follow-up or feedback.

5) Copies of manuscripts (published or unpublished) derived from research performed under the contract and copies of all abstracts, manuscripts, preprints and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period.

6) An anticipated work plan for the next quarter.

7) Any additional information requested within the Statement of Work, or as requested by the Project Officer.

II. Annual Reports

The fourth Quarterly Report shall represent the Annual Report and follow the format and time schedule for the Quarterly Report. The Annual Report shall summarize progress for the entire Contract year and be submitted as with the Quarterly Report on the 15th of the month following the end of the reporting period.

III. Final Report

The Contractor shall submit copies (as specified for the Quarterly Report above) of the Final Report that document and summarize the results of the entire contract period of performance. This report will be submitted no later than the completion date of the Contract. The report shall include the following:

(A) A cover page that lists the contract number and title, performance period covered, author(s), Contractor's name and address, telephone number, fax number, e-mail address, and submission date.
(B) An introduction describing the purpose and scope of the effort, including a summary of salient results, not to exceed 200 words.
(C) An executive summary, to include an overview of the fulfillment of production goals and the specific aims set forth in the Contract.
(D) A detailed description of all the work performed; the results obtained; technologies, reagents, and data generated; and a discussion of the relevance of the results and impact on the NHP research community.

IV. Other Deliverables

Any additional items or reports required in the Statement of Work within the time frame stated. In addition, delivery at least one (1) month prior to the contract completion date any equipment supplied or procured under this contract, the complete database and source codes of data generated, protocols, materials provided, and all genetic, hardware, software, equipment, biochemical, and biological materials acquired, developed, or inventoried during the contract period.

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.

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal Or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed For Debarment over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)

52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data-Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
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.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright

		Infringement ($100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a)(2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-25	Feb 2002	Prompt Payment, Alternate I (Feb 2002)
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	July 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
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.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)

52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

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

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
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:

Alternate II, (APRIL 1998) of FAR Clause 52.215-2, AUDIT AND RECORDS—NEGOTIATION (JUNE 1999) is added.

FAR Clause 52.215-15, PENSION ADJUSTMENTS AND ASSET REVERSIONS (DECEMBER 1998), is deleted in its entirety.

FAR Clause 52.215-18, REVERSION OR ADJUSTMENT OF PLANS FOR POST RETIREMENT BENEFITS (PRB) OTHER THAN PENSIONS (OCTOBER 1997) is deleted in its entirety.

FAR Clause 52.215-19, NOTIFICATION OF OWNERSHIP CHANGES (OCTOBER 1997), is deleted in its entirety.

FAR clause 52.216-7 ALLOWABLE COST AND PAYMENT (MARCH 2000) is modified in paragraph (a)to delete the words "subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute the words "45 CFR part 74, appendix E".

ALTERNATE I of FAR Clause 52.216-11, COST CONTRACT—NO FEE (APRIL 1984), is added.

ALTENATE II (OCTOBER 2001) of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is added.

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 52.216-15, Predetermined Indirect Cost Rates (APRIL 1998).

FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference.....

[ ]Offeror elects to waive the evaluation preference."

ALTERNATE I (OCTOBER 1998), FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCTOBER 1999).

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

FAR 52.227-16, Additional Data Requirements (JUNE 1987).

FAR 52.230-2, Cost Accounting Standards (APRIL 1998)

FAR 52.230-5, Cost Accounting Standards- Educational Institution (APRIL 1998)

FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

FAR 52.232-18, Availability of Funds (APRIL 1984).

FAR 52.242-3, Penalties for Unallowable Costs (October 1995).

FAR 52.243-2 Changes—Cost Reimbursement (August 1987), Alternate V (April 1984).

FAR 52.246-23 Limitation of Liability (FEBRUARY 1997).

FAR 52.246-24, Limitation of Liability – High Value Items (February 1997).

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).

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)

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.

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.

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

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.
52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
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)).
52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
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).

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.

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 18, 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):

1. Technical Proposal Cover Sheet
2. Summary of Related Activities
3. Government Notice for Handling Proposals
4. Project Objectives NIH Form 1688-1

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

1. NIH-2043, Proposal Summary and Data Record
2. Small Business Subcontracting Plan Format (if applicable)
3. Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

1. NIH (RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
2. Instructions for Completing Form NIH-2706
3. (RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
4. Handling of Proprietary Data
5. Safety and Health, HHSAR Clause 352.223-70
6. Report of Government Owned, Contractor Held Property
7. Disclosure of Lobbying Activities, OMB Form LLL

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 NIH-NIAID-DAIT-04-24
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**
Contract Specialist Contract Management Branch, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	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 150 PAGES (FOR EACH OF PARTS I AND II). PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: 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-DAIT-04-24
RFP Title: "Development of Immune Monitoring Reagents and MHC Typing Technologies for Non-Human Primates"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by February 18, 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: Carl Newman
RFP-NIH-NIAID-DAIT-04-24
FAX# (301) 480-5253
Email : cnewman@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).

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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.

a. NAICS CODE AND SIZE STANDARD

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

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

b. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that multiple awards 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 five years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

c. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of the RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 525% effort or 9,940 hours per year for Part I (Non-Human Primate Reagent Development and Production) and 635% total effort or 13,208 hours per year for Part II (MHC High Throughput Technologies Development). This information is furnished for the offeror’s information only and is not to be considered restrictive for proposal purposes.

d. **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.

e. **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.

f. **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.

g. **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.

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

i. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2
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:
Brenda J. Velez
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
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)

j. **LATE PROPOSALS AND REVISIONS (HHSAR 352.215-70)**
Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.
(End of provision)

k. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**
Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

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

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

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.

1)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).

2) 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.

3) 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.

4) Evaluation of Proposals

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

5) 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.

6) 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.

7) 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:

a. to the cognizant audit agency and the General Accounting Office for auditing.
b. to the Department of Justice as required for litigation.
c. to respond to congressional inquiries.
d. to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

8) 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.

9) 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, to this RFP is an example of such a plan.

1. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

2. 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.

3. The offeror understands that no contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer. This plan will be incorporated into the contract as a material part thereof.

(a) 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.

(b) 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.

(c) 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.

(d) 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.

(e) 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.

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.

10) Salary Rate Limitation in Fiscal Year 2004

Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through any contract at a rate in excess of the applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "Institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

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

(applicable information to be included at award)

*Currently this amount is $(to be inserted in contract) and will remain at this level until such time as the Executive Level I is increased. See the following web site for Executive Schedule rates of Pay:

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).

11) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c)Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been

managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

12) Institutional Management of Conflicting Interests

a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

public disclosure of significant financial interests;
monitoring of research by independent reviewers;
modification of the research plan;
disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
divestiture of significant financial interests; or
severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

13) ROTC Access and Federal Military Recruiting on Campus

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

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

military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

14) Prohibition on Contractor Involvement with Terrorist Activities

The Offeror 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).

15) 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):

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

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

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

Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program

The awardee is responsible for ensuring that all work under this 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 .

16) Guidance Regarding Federal Government Collaborations

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or appearance of a conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter

must be signed by both the designated agency ethics official (DAEO) 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 appearance of a conflict of interest.

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.

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.

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

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

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

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

(3) 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.

(4) 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) Royalties

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

c) 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.

d) 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.

e) 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)

f. Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

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

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.

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.

g) Subcontractors

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

1. Willingness to perform as a subcontractor for specific duties (list duties).
2. What priority the work will be given and how it will relate to other work.
3. The amount of time and facilities available to this project.
4. Information on their cognizant field audit offices.
5. How rights to publications and patents are to be handled.
6. 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

h) Proposer's Annual Financial Report

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

i) 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.

j) Travel Costs/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.

k) 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.

SECTION M - EVALUATION FACTORS FOR AWARD

Reagent Development for Monitoring Immunity in Non-Human Primates
DAIT-04-24

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against two factors. The factors in order of importance are: (1) technical merit and (2) cost. Although technical factors are of paramount consideration in the award of the contract, cost/price is also important to the overall contract award decision. However all evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government. In accordance with FAR 15.3, the award will be subject to a cost realism analysis by 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 carefully evaluated. Each proposal must document the feasibility of its plan to successfully achieve the objectives of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. TECHNICAL EVALUATION CRITERIA

The technical evaluation committee will use these evaluation criteria when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criteria	**Weight**
I. PART I	
Non-Human Primate Reagent Development and Production	**Total: 100 points**

A. Technical Approach/Methodology **50 points**

Strength and merit of the documented ability of the Offeror to design, develop, and implement programs to develop, optimize, evaluate, produce, purify, and distribute NHP reagents and reagent assays, where applicable, for immune-monitoring, immune-modulation or immune-based therapy. **(20 points)**

Adequacy, logic, comprehensiveness, and scientific and technical appropriateness of the proposed technical approaches and methodologies to be used to conduct the tasks specified in the Statement of Work, including, but not limited to reagent and assay development, validation, production and purification. Completeness of description of the proposed methodologies and thoroughness of discussion of potential problems and appropriate alternative approaches to be use to conduct the proposed tasks, including the three specific (Category 1-3) proposals for reagent development and production presented in the Technical Proposal. **(20 points)**

Scientific rationale, justification, suitability, and feasibility of specific NHP reagent needs identified and justified by the Offeror. Adequacy of the database and website development plans. **(10 points)**

B. Personnel **35 points**

Principal Investigator: Documented training, expertise, leadership, and availability of a Principal Investigator with the technical and administrative competence to successfully plan, direct and manage a project of this size and complexity. Relevance and quality of work in accordance with the requirements of the RFP. **(20 points)**

Scientific and Technical Staff: Documented training, experience, and availability of the proposed professional, technical and support staff and their documented capabilities to perform their roles with respect to the proposed studies, including expertise gained from participating in projects of a similar nature, the logistical adequacy of the staffing plan for the project and spectrum of expertise offered. The above information shall be provided for staff working at the contract site as well as for subcontractors and consultants. **(15 points)**

C. Facilities, Resources and Equipment **15 Points**

Documented availability and adequacy of facilities, equipment, and resources, necessary to conduct all phases of the proposed and specified tasks

Criteria **Weight**

PART II

MHC High-Throughput Technologies Development **Total: 100 points**

A. Technical Approach/Methodology **50 points**

a) Strength and merit of the documented ability of the Offeror to design, develop, and implement programs to develop, optimize and validate NHP high-throughput molecular tools and technologies for the identification and typing MHC Class I and Class II alleles and haplotypes, as specified in the SOW.

(20 points)

b) Adequacy, logic, comprehensiveness, feasibility and scientific and technical appropriateness of the proposed technical approaches and methodologies to be used to conduct the tasks specified in the Statement of Work. Completeness of description of the proposed methodologies and thoroughness of discussion of potential problems and appropriate alternative approaches to be used to conduct the proposed tasks in the SOW. Knowledge of the state-of-the science.

(20 points)

c) Demonstrated knowledge of the state-of-the-science. Adequacy of the database, website, and training development plans. **(10 points)**

B. Personnel **35 points**

a) Principal Investigator: Documented training, expertise, leadership, and availability of a Principal Investigator with the technical and administrative competence to successfully plan, direct and manage a project of this size and complexity. Relevance and quality of work.

(20 points)

b) Scientific and Technical Staff: Documented training, experience, and availability of the proposed professional, technical and support staff and their documented capabilities to perform their roles with respect to the proposed studies, including expertise gained from participating in projects of a similar nature. The logistical adequacy of the staffing plan for the project and spectrum of expertise offered. The above information shall be provided for staff working at the contract site as well as for subcontractors and consultants.

(15 points)

C. Facilities, Resources and Equipment **15 Points**

Documented availability and adequacy of facilities, equipment, and resources, necessary to conduct all phases of the proposed and specified tasks.